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RESEARCH ARTICLE

Assessing risk of adverse drug reactions in the elderly: a feasibility study

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Abstract

Background Adverse drug reactions are common in Australian general practice and can be a cause of, or contribute to, preventable hospital admissions. Developing practical tools to assist in identifying patients who are at high risk of serious adverse drug reactions is an important step in preventing these hospitalisations. *Objective* The aims of the study were to apply the Prediction of Hospitalisation due to Adverse Drug Reactions in Elderly Community-Dwelling Patients (PADR-EC) Score to assess the risk of medication-related hospitalisation among patients aged ≥ 65 years attending a rural general practice, and to investigate general practitioners' acceptance of the PADR-EC Score. *Setting* The project was based in a multicentre rural general practice in southern Tasmania, Australia. *Method* We conducted a cross-sectional study wherein the PADR-EC score was administered to patients aged ≥ 65 years attending a general practice. A focus group of general practice doctors was conducted and thematic analysis of the transcript used to explore their views regarding the utility of the PADR-EC score. *Main Outcome Measures* Successful application of the PADR-EC Score and an evaluation of general practitioners' acceptance of the PADR-EC Score are the two outcome measures of the project. *Results* The PADR-EC score was applied by the practice pharmacist and reported to GPs for 428 patients aged ≥ 65 years, with 24.8% classified as high-risk. The focus group found the PADR-EC score helped raise awareness of the risk of adverse drug reactions in the general practice setting. Doctors demonstrated good understanding of the PADR-EC Score and there were no negative reactions to the delivery model used. No changes to prescribing were implemented directly as a result of the PADR-EC Score, but more caution was used when doctors provided their usual clinical care. *Conclusion* Doctors used the PADR-EC score to complement their decision making. The PADR-EC Score was used as a reminder to review existing medication lists, follow-up on pathology results that may impact drug treatment and assess patients for prevalent ADRs. Further research is needed to validate the PADR-EC score in this setting.

Keywords Adverse effect · Aging · Primary care · Risk factors · Safety

Impact on practice

- The PADR-EC Score may help identify patients at higher risk of adverse drug reactions (ADRs), and raise awareness of ADRs from medications in general, in the general practice setting.
- The PADR-EC Score could help identify patients who require additional clinical care from general practitioners or other healthcare providers.
- Pharmacists working as part of a multidisciplinary team in the general practice setting are able to effectively apply the PADR-EC Score in a systematic manner.

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Introduction

Australia has an aging population, and people aged ≥ 65 years now make up 15% of the nation's population [1]. The growing population of older people is associated with increasing demand on health and social services and increasing costs. Over 45% of the Australian population have at least one chronic disease, with those living in rural and other areas of low socioeconomic status (SES) often experiencing higher rates of chronic disease and poorer overall health than urban populations [2]. Medication use is common among older Australians, with an estimated two-thirds of people over 60 years using four or more drugs daily, either prescription or non-prescription [3].

An adverse drug reaction (ADR) is a response to a medicinal product that is noxious and unintended [4]. Such events may include physical, psychological or emotional suffering in the patient. The combination of polypharmacy, advanced age comorbidities are associated with an increased risk of an ADR [5].

Both the overall number of ADRs and cost per hospital admission across all Australian hospitals have risen over the last decade [2]. ADRs contribute to 2–3% of all hospital admissions across Australia, while among those aged ≥ 65 years the rate could be as high as 20% and 30% of all admissions [6]. In 2016–2017, Australians aged ≥ 65 years accounted for 42% of all hospital separations and 48% of the total number of patient days in hospital. Additionally, patients from rural communities or low SES areas had a longer stay in hospital compared to those from urban areas [7].

Data gathered from Tasmanian hospitals in 2014–2015 show that over a one-year period 18.9% of unplanned admissions involving people aged ≥ 65 years were potentially ADR-related [8]. The Prediction of Hospitalisation due to Adverse Drug Reactions in Elderly Community-Dwelling Patients (PADR-EC) Score was derived using data from a prospective, cross-sectional study of patients ≥ 65 year admitted to an Australian public hospital. The predictive score was then applied to a validation cohort with expert consensus used to confirm ADR-related hospital admission [9]. Following on from this validation study we wanted to investigate the risk profile of older patients in primary care using the PADR-EC score.

Aim

The objective of the study was to apply the PADR-EC Score to patients aged ≥ 65 years attending a rural general practice, and to evaluate physicians' responses to and perception of the tool.

Ethics

Ethics approval was obtained from the Tasmanian Health and Medical Human Research Ethics Committee (reference H0017301).

Method

A cross-sectional study in a single Tasmanian general practice was conducted to determine an estimate of the prevalence of ADR-related risk in this setting. The study was descriptive and there was no measurement of clinical changes or estimates of adverse events that may have been prevented.

The PADR-EC score was applied to patients aged ≥ 65 years who presented to the Huon Valley Health Centre (HVHC) over a 28-day period in July 2018. The HVHC is a large multi-centre practice in the Huon Valley area with clinics in Huonville, the municipal centre, and Cygnet, a smaller outlying community. Both are approximately 40 km south of Hobart, the state capital of Tasmania. The Huon Valley is classed as an Outer Regional area [10] with the towns of Huonville and Cygnet both having a Socio-Economic Indexes for Areas (SIEFA) ranking in the lowest 20% of the nation [11]. Access to health services, reduced access to educational and employment opportunities and lower income levels are factors that contribute to poorer health outcomes in rural populations [2].

Adults ≥ 65 years who have visited the practice in the last two years make up approximately 17% of the practice's patient-base. Almost 70% of this cohort had attended the practice in the preceding six months. The PADR-EC score was originally developed for use in patients aged ≥ 65 years so only this age-group was included in the study.

The HVHC has five general practitioners working at the practice each weekday across both sites. Experience levels of practitioners ranges from interns (first year of registered medical practice) to fellows of the Royal Australian College of General Practice (a specialist general practice qualification awarded after several years of practice). It was estimated that each general practitioner would consult an average four patients aged ≥ 65 years every day, suggesting that over 200 individuals would be reviewed. The HVHC was the first private general practice to fully integrate a clinical pharmacist into their workforce in Tasmania with proactive pharmacovigilance services included in their scope of practice.

Prior to the data collection phase, the whole practice, and physicians in particular, were provided with background information about the study protocol and the PADR-EC score. The clinical relevance of the score was also explained; that is, patients with a PADR-EC score of ≥ 6 were at three

times the risk of ADR-related hospitalisation than those with a PADR-EC score of < 6 [9]. Patients were only assessed once during the 28 days of data collection.

To apply the PADR-EC score the pharmacist reviewed each physicians' appointments for the following day. Patients who were ≥ 65 years at the time of their appointment were identified and their medication records and clinical correspondence reviewed. Their PADR-EC score was calculated from the following factors: drug changes in the preceding three months (2 points), renal failure (2 points), dementia (2 points), number of antihypertensives (1–2 antihypertensives 3 points; ≥ 3 antihypertensives 5 points) and use of anticholinergic medications (2 points) [9]. An entry was made in the patients' electronic medical record to indicate the PADR-EC score had been calculated. As was noted in the validation study [9], a score of 6 was found to provide the best balance between sensitivity (72.2%) and specificity (58.0%)—thus PADR-EC scores ≥ 6 was recorded as "high" and "low for scores < 6. Each entry was coded as "PADR-EC score" as the indication for accessing the notes. The notes entry used for every patient who received a PADR-EC score during the data collection period is shown in Box 1.

Additional information was recorded to enable the Charlson Comorbidity Index (CCI) to be calculated [12]. Definitions of number of medications and change of medication were taken from the original paper by Nair et al. [9]. A medication change was defined as addition of a new drug or deletion of an existing drug or a change in drug doses in the three months preceding the patient's admission [9]. The socioeconomic status of the participant was measured according to residential postcode using the Index of Relative Socio-Economic Advantage and Disadvantage (IRSAD). A lower score reflects a relative greater disadvantage, while a higher score reflects a greater advantage. The IRSAD incorporates and balances elements of both socioeconomic advantage and disadvantage, and was thought an appropriate measure for the effect social factors may have on medication use and ADRs [13]. Data on specific medications (or groups of medications) was collected if the literature suggested they were associated with the occurrence of ADR in any setting. The data was de-identified prior to analysis by removing the names and addresses of both patients and physicians.

Parametric data was summarised with means and standard deviations (SD) and proportions (as percentages) were used for categorical variables. The data was stratified by the outcome of the PADR-EC score ("high" for a score ≥ 6; "low" for a score < 6). To investigate significant associations between variables and the dichotomised PADR-EC score, a Student's *t* test was used for normally distributed numerical and a Chi squared test was used on categorical variables. A Mann–Whitney *U* test was used where the data were not normally distributed. Statistical significance was set at $p < 0.05$.

A focus group discussion was held at the end of the one-month data collection period. All 12 physicians at the practice were invited to participate with the intention of capping the group at maximum recommended size of 10 participants so that all participants have an opportunity to voice their opinions [14]. It was hoped that such purposive sampling would provide a group with a range of personal and professional experiences and views.

A semi-structured group discussion was conducted and electronically recorded with participant consent. When adequate discussion in a given area had occurred the conversations was progressed. Each participant was assigned a code to allow them to be identified during transcription and for anonymous use during analysis. The discussion was transcribed verbatim, coded and analysed using NVivo for Windows 10 [15].

A realist, semantic approach to thematic analysis was used to identify, interpret and present key patterns in the transcript using the methods described by Braun and Clarke [16]. Coding of the transcript was an inductive process. When repeated concepts were identified in the transcript they were coded according to the semantics used. Following initial coding, overarching themes were formed that more succinctly described larger concepts that were expressed in the transcript. Where necessary, the themes were refined, and sub-themes formed to describe to describe more specific aspects or the structure of the parent theme.

Results

Quantitative data was collected from patients (n = 428) over four weeks in July 2018. There were 1162 patients aged ≥ 65 years in the practice's database at the beginning of the study who had presented to the practice three or more times in the preceding six months. The 428 individual patients included in this project represented 36.8% of patients who were most likely to present to the practice.

There were 106 patients (24.8%) who were high-risk according to their PADR-EC score. The mean PADR-EC score for all patients was 4.10 (SD 2.0). A description of the characteristics of patients is shown in Table 1 and prevalence of the diseases which contribute toward the CCI is shown in Table 2.

Box 1 Medical Director entry

This patient has a HIGH/LOW risk of adverse drug reaction according to the PADR-EC score
Patients with a high PADR-EC score are hospitalised due to ADR at more than three times the rate of those with a low score
Interventions to lower the risk of ADR may be appropriate for high-risk patients

Table 1 Characteristics of patients and PADR-EC score risk classification

	Characteristic		High PADR-EC score	Low PADR-EC score	*p*
n (%)		428 (100)	106 (24.8)	322 (75.2)	
Sex (n, %)	Female	235 (54.9)	57 (53.8)	178 (55.3)	0.79
	Male	193 (45.1)	49 (46.2)	144 (44.7)	
Age (mean, SD)		74.19 (6.8)	77.35 (7.3)	73.14 (6.4)	< 0.001
Aboriginal or Torres Strait Islander (n, %)	No	415 (97.0)	100 (94.3)	315 (97.8)	0.07
	Yes	13 (3.0)	6 (5.7)	7 (2.2)	
Smoking status (n, %)	Non-smoker	394 (92.1)	101 (95.3)	293 (91.0)	0.16
	Smoker	34 (7.9)	5 (4.72)	29 (9.0)	
IRSAD[a] (mean, SD)		936.88 (45.7)	928.42 (42.4)	939.66 (46.5)	0.03
PADR-EC score (n, %)			106 (24.8)	322 (75.2)	
PADR-EC score (mean, SD)		4.10 (2.0)	7.67 (1.2)	2.93 (1.9)	< 0.001
Charlson Comorbidity Index (mean, SD)		4.72 (2.3)	6.42 (2.2)	4.16 (2.1)	< 0.001
Renal function (mL/min/1.73 m^2, SD)		72.21 (17.0)	46.60 (12.8)	79.2 (9.81)	< 0.001
Renal failure[b] (n, %)		89 (20.8)	65 (73.0)	24(27.0)	< 0.001
Liver function (ALT; mean, SD)		32.4 (24.7)	22.70 (15.99)	25.80 (27.01)	0.28
Location	Huonville	268 (62.6)	75 (70.8)	193 (59.9)	0.046
	Cygnet	160 (37.4)	31 (29.3)	129 (40.1)	
Number of medications (mean, SD)		6.15 (4.4)	9.98 (4.7)	4.87 (3.4)	< 0.001
Number of antihypertensives (n, %)	0	151 (35.5)	1 (0.9)	150 (46.6)	< 0.001
	1–2	213 (50.0)	50 (47.2)	163 (50.6)	
	≥ 3	62 (14.6)	55 (51.9)	7 (2.2)	
Specific medication (n, %)	Benzodiazepine or Z-drug[c]	24 (5.6)	8 (7.6)	16 (5.0)	0.32
	Tricyclic antidepressant[d]	32 (7.5)	22 (20.8)	10 (3.1)	< 0.001
	Digoxin	10 (2.3)	4 (3.8)	6 (1.9)	0.26
	Oral anticoagulant[e]	52 (12.2)	21 (19.8)	31 (9.7)	0.006
	Antiplatelet[f]	100 (23.4)	39 (36.8)	61 (19.0)	< 0.001
	Opiate[g]	59 (13.8)	20 (18.9)	39 (12.2)	0.08
Medication change in 3 months prior (n, %)	No change	156 (36.5)	8 (7.5)	148 (47.0)	< 0.001
	Change	265 (61.9)	98 (92.5)	167 (53.0)	
Anticholinergic agents (n, %)		40 (9.4)	26 (24.5)	14 (4.3)	< 0.001

[a]*IRSAD* Index of relative socio-economic advantage and disadvantage

[b]eGFR < 60 mL/min/1.73 m^2

[c]Z-drug = zolpidem, zopiclone

[d]Includes: amitriptyline, nortriptyline, doxepin

[e]Oral Anticoagulant = warfarin, apixaban, dabigatran, rivaroxaban

[f]Antiplatelet = aspirin, clopidogrel, ticlopidine

[g]Opiate = codeine, morphine, oxycodone, methadone, tapentadol, tramadol, buprenorphine

There was a significant age difference among patients with a high and low PADR-EC risk categorisation. Compared to participants with a low PADR-EC score, those who scored high were significantly older (73.1 years vs. 77.4 years; $p < 0.001$). The CCI was higher amongst those with a high compared with a low PADR-EC score (6.42 vs. 4.16; $p < 0.001$), as was the number of medications being used (9.98 vs. 4.87; $p < 0.001$). Level of socioeconomic advantage among women, as measured by IRSAD, approached statistical significance ($p = 0.08$) with average scores for females and males of 940.4 (46.0) and 932.6 (45.1) respectively. The median number of medications used per patient was 6 (range 0–34). Polypharmacy (defined as use of ≥ 5 medications) was evident in 57.4% of the patients reviewed. A comparison of CCI components between low- and high-risk patients according to the PADR-EC score is shown in Table 3.

The group discussion showed that GPs had a good understanding of what the PADR-EC Score represented. Several physicians understood the score to reflect the risk of *any* ADR occurring, and not specifically a reflection

Table 2 Prevalence of conditions

Condition	n (%)
Musculoskeletal disease other	209 (48.8)
Hypertension	200 (46.7)
Peptic ulcer other	108 (25.2)
Diabetes non-insulin dependent	82 (19.2)
Asthma	53 (12.4)
COPD	49 (11.4)
Urinary disease other	46 (10.7)
Ischaemic heart disease without angina	43 (10.0)
Malignancy	22 (5.1)
Rheumatoid or seropositive arthritis	21 (4.9)
Heart failure	19 (4.4)
Stroke (CVA)	18 (4.2)
Diabetic peripheral neuritis or neuropathy	17 (4.0)
Acute myocardial infarction	16 (3.7)
Transient cerebral ischaemia	15 (3.5)
Atherosclerosis or peripheral vascular disease	13 (3.0)

of the risk of ADR-related hospitalisation. No objections to a pharmacist delivering the intervention were recorded and all physicians were satisfied with the delivery method and format of the PADR-EC Score. Having the PADR-EC Score directly entered into the patients' notes by another health professional was seen as a positive feature of the project.

GPs did not feel that the PADR-EC Score directly changed their prescribing patterns or make them more inclined to modify existing medication treatment. However, the PADR-EC Score was used as a reminder to review existing medication lists, follow-up on pathology results that may impact drug treatment and monitor patients for prevalent ADRs.

GPs felt the PADR-EC Score could be improved by having its components more clearly identifiable. There was agreement that altering treatment with the aim of reducing the PADR-EC Score was not intended to be the outcome of applying the score. There was concern that a low score may cause a relative lack of attention to medication-related issues, and that additional testing of the tool would provide greater confidence in its validity.

Some participants felt the PADR-EC Score would also be useful for pharmacists who could coordinate the risk-reduction response, including conducting a medication review if warranted. It was thought that recommendations from the medication review would be more likely to be accepted if the PADR-EC Score reinforced the need for risk-reduction.

Table 3 CCI components in participants with a high and low PADR-EC score

Condition	High	Low	*p*
Malignancy (n, %)	4 (3.8)	18 (5.6)	0.46
Leukaemia	0 (0.0)	4 (1.2)	0.56
Malignant neoplasm blood other	1 (1.0)	2 (0.6)	0.73
HIV-infection/AIDS	0 (0.0)	1 (0.3)	0.77
Duodenal ulcer	0 (0.0)	2 (0.6)	0.68
Peptic ulcer other	32 (30.2)	76 (23.6)	0.78
Acute myocardial infarction	6 (5.7)	10 (3.1)	0.23
Ischaemic heart disease without angina	16 (15.1)	27 (8.4)	0.046
Heart failure	18 (17.0)	1 (0.3)	< 0.001
Hypertension	72 (67.9)	128 (39.8)	< 0.001
Transient cerebral ischemia	1 (0.9)	14 (4.3)	0.10
Stroke (CVA)	8 (7.5)	10 (3.1)	0.048
Atherosclerosis or peripheral vascular disease	7 (6.6)	6 (1.9)	0.014
Rheumatoid or seropositive arthritis	7 (6.6)	14 (4.3)	0.35
Musculoskeletal disease other	62 (58.5)	147 (45.7)	0.022
Organic psychosis other	0 (0.0)	1 (0.3)	0.77
COPD	19 (17.9)	30 (9.3)	0.016
Asthma	19 (17.9)	34 (10.6)	0.046
Diabetes insulin dependent	2 (1.69)	0 (0.0)	0.032
Diabetes non-insulin dependent	35 (33.0)	47 (14.6)	< 0.001
Urinary disease other	11 (1.4)	35 (10.9)	0.89
Diabetic peripheral neuritis or neuropathy	10 (9.4)	7 (2.2)	0.001
(Diabetic) Retinopathy	4 (3.8)	1 (0.3)	0.004

Discussion

The study found that almost a quarter (24.8%) of men and women aged ≥65 years attending a rural general practice were classified as being at high risk of ADR-related hospital admission by the PADR-EC score. The delivery approach of the PADR-EC score used in this study was acceptable to physicians in the practice. There was an overall acceptance that the PADR-EC score matched well with the physicians' assessment of the potential for ADR in patients.

The PADR-EC score was found to be a simple and efficient predictive score that identifies patients who currently live in the community but are potentially at risk of ADR-related hospitalisation. As was recognised by several physicians in the focus group discussion, risk is determined by more than just the crude number of medications being taken by a patient. A more nuanced approach to determining risk of ADR involves considering a combination of pharmacological, physiological and environmental determinants. In contrast to many previously published predictive tools, the PADR-EC score acknowledges that a variety of factors contribute to an increased risk of ADR in the elderly.

The PADR-EC score can be completed without any clinical interpretation of medication or physiology as it does not include any implicit criteria. The medication regimen is taken on face-value with physiological parameters being independent factors for scoring purposes. Using explicit criteria in the PADR-EC Score avoids inter-operator variation that has been reported with tools, such as the Medication Appropriateness Index (MAI), that require time consuming and judgement-based assessment of patient records [17]. This is an advantage that may allow a greater range of health-professionals throughout primary care to use the PADR-EC Score.

Unlike population based predictive tools, the PADR-EC Score can be applied to individual patients at any time point in the care continuum with easily accessible information; that is, at or after discharge, or at any juncture in primary care where a significant change may indicate a need to assess the risk of ADR-related hospitalisation. Tools that require information unavailable to general practitioners, are developed for use in other settings (e.g. hospital or aged-care facilities) or require revision when specific medications become obsolete or clinical guideline change are less suitable for regular use in primary healthcare [5, 17–19]. Suitability for use in the intended health-setting was noted by Dimitrow et. al. as a major determinant of an effective predictive tool [20].

Participants of the focus group discussion had generally positive perceptions of the PADR-EC Score as it was used in this study. The group consisted of a cohort of senior physicians who were experienced in general practice. Assessment and assimilation of information from a variety of sources and formats is standard practice in general practice. As such, providing a summary measure of several known factors in the PADR-EC Score was unlikely to cause any confusion for physicians. They were also broadly accepting of the new clinical roles of other health professionals and were used to a proactive, patient-centred approach to primary healthcare delivery. This attitude may have contributed substantially to the positive view of the PADR-EC Score.

Although pre-study information was provided both verbally and in written form to physicians, there was still a perception that the PADR-EC Score represented a general level of risk of *any* ADR, and not specifically the risk of ADR-related hospitalisation. There may be a need for further education about what the PADR-EC Score represents if it is used in the future which may then alter physicians' understanding, use and acceptance of the intervention.

The delivery of the PADR-EC Score in this project was simple and acceptable to physicians. Delivering the PADR-EC Score via a fully integrated pharmacist recognises the role and enhances the positive perception of pharmacist working in the general practice setting. Although well received, however, the cost effectiveness and improved clinical outcomes were not investigated in this study. Additionally, the optimal time and frequency to use the PADR-EC Score was not investigated here and have a bearing on its use in the future.

Analysis of the focus group confirms that physicians are willing, and indeed enthusiastic, about working as part of a multidisciplinary team in general practice. Using a new approach to detect and estimate the risk of an individual patient experiencing an ADR is welcomed by physicians, although a better understanding of the robustness of the PADR-EC Score would be desirable for future use. Obstacles to reducing potentially inappropriate medication use in the elderly that were reinforced by this study included lack of time during appointment for thorough medication review, incomplete information about patients (e.g. medications obtained via other prescribers, previous history of ADR or other clinical factors) and a thorough understanding of the importance of ADR to patients or the health system.

Further research is required to explore what actions physicians (and the wider healthcare team) should make in response to a patient being identified as being at high-risk of an ADR. The current study suggests that using the PADR-EC Score could support review of medication lists and vigilance when prescribing new medications. In addition, evidence-based interventions to mitigate potential ADR-related harm in high-risk PADR-EC Score patient should also be considered. A systematic way to incorporate additional patient monitoring, ensuring data completeness,

assessing social supports and application of specific medication-focused intervention should be considered. A better use of primary healthcare resources may reduce the number of preventable ADR experienced in the community.

Adaption of the PADR-EC score for Aboriginal and/or Torres Strait Islander people aged ≥ 55 years may be appropriate. This study made no allowance for the effect Aboriginal and/or Torres Strait Islander status has on health-related predictions. The study was only able to accommodate one focus group discussion consisting of six GPs. A sample of this size is considered acceptable for qualitative studies however there was under-representation of younger and less experienced physicians. It would have been valuable to gain some understanding of how the PADR-EC score was perceived and used among a more diverse range of practitioners. The same project methodology may not be possible or as well received in other practices that do not already welcome a multidisciplinary approach to primary care and may make even the most robust predictive tool ineffective. Usefulness of the IRSAD score as a measure of SES was limited as patients were scored at a postcode level. This masks variation within a location and may have caused the effect of SES to be under or over-estimated.

Conclusion

The study showed that the PADR-EC Score could be applied to general practice patients aged ≥ 65 years by a clinical pharmacist. GPs found the PADR-EC Score useful in complementing their decision making. The PADR-EC Score was used as a reminder to review existing medication lists, follow-up on pathology results that may impact drug treatment and assess patients for prevalent ADRs.

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