Real time monitoring of opioid prescriptions: DORA and her big brother ERRCD

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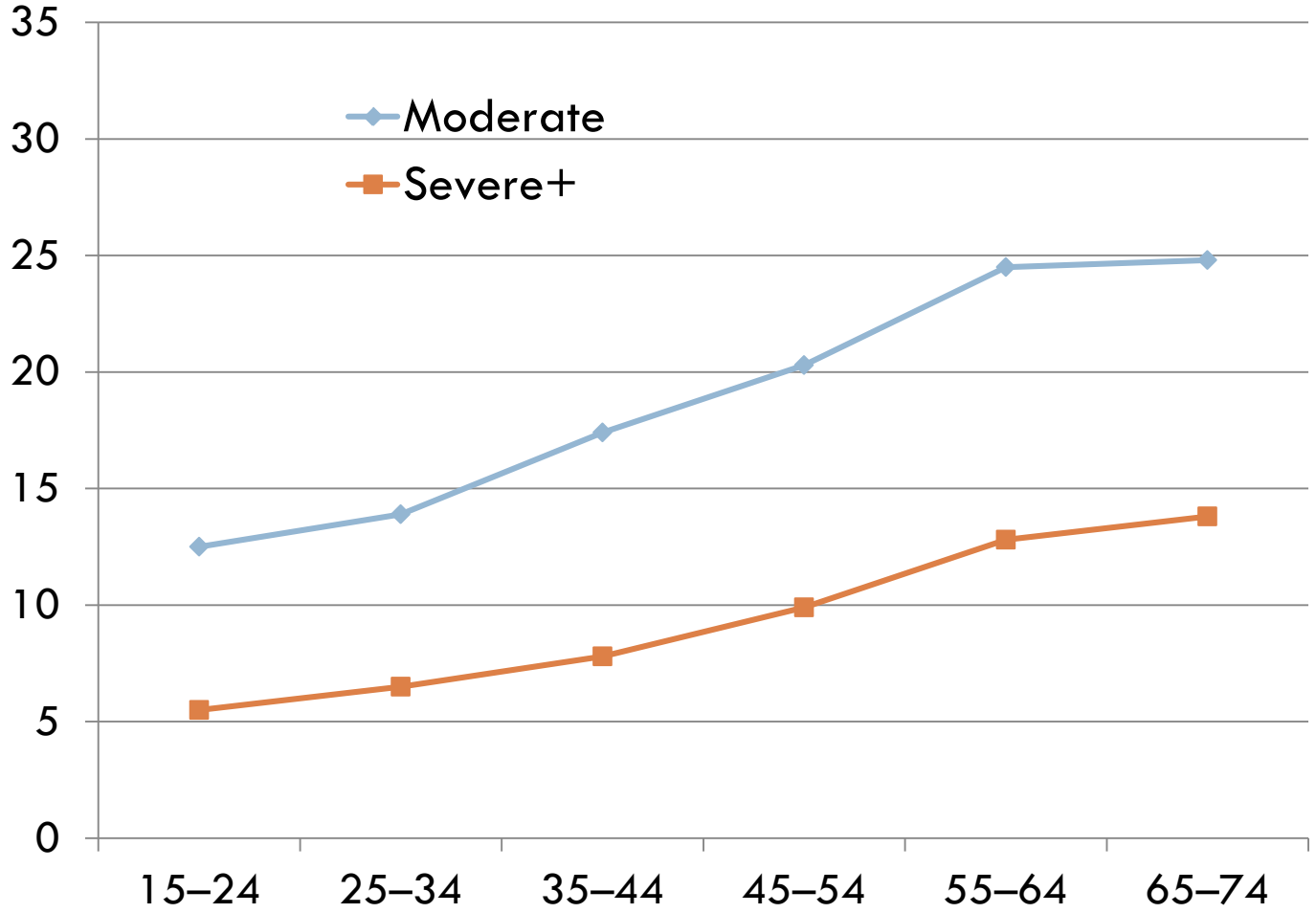
Disclaimer

Pain in Australia (past 4 weeks)

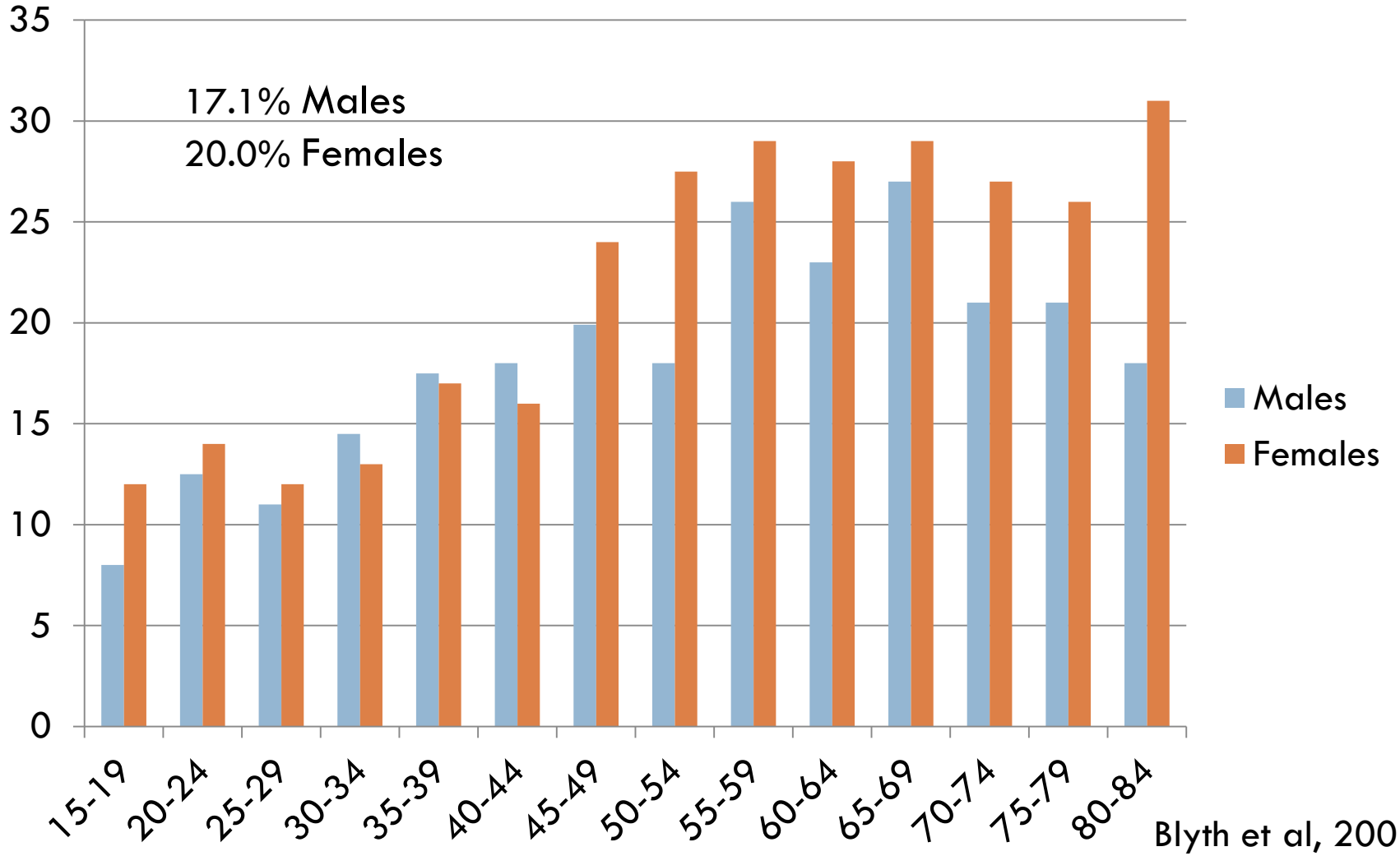


Moderate: 19%
~3,040,300 *18+*
(1995: 12%
~1,658,500 18+)

Severe+: 10%
~1,552,900 18+
(1995: 7%
~972,900 18+)

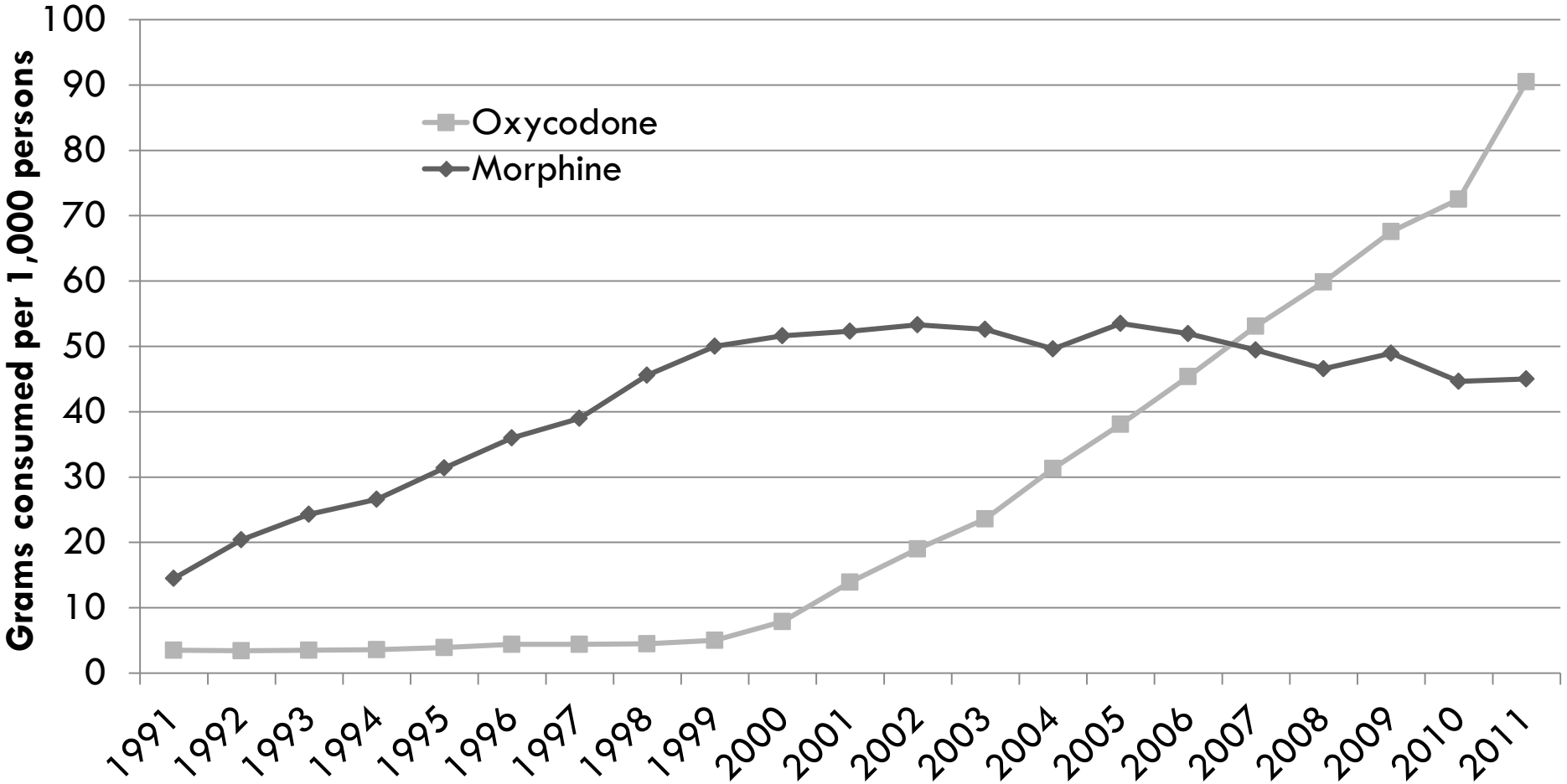
Source: 2007–08 ABS National Health Survey

Chronic Pain Prevalence in Australia



Blyth et al, 2001

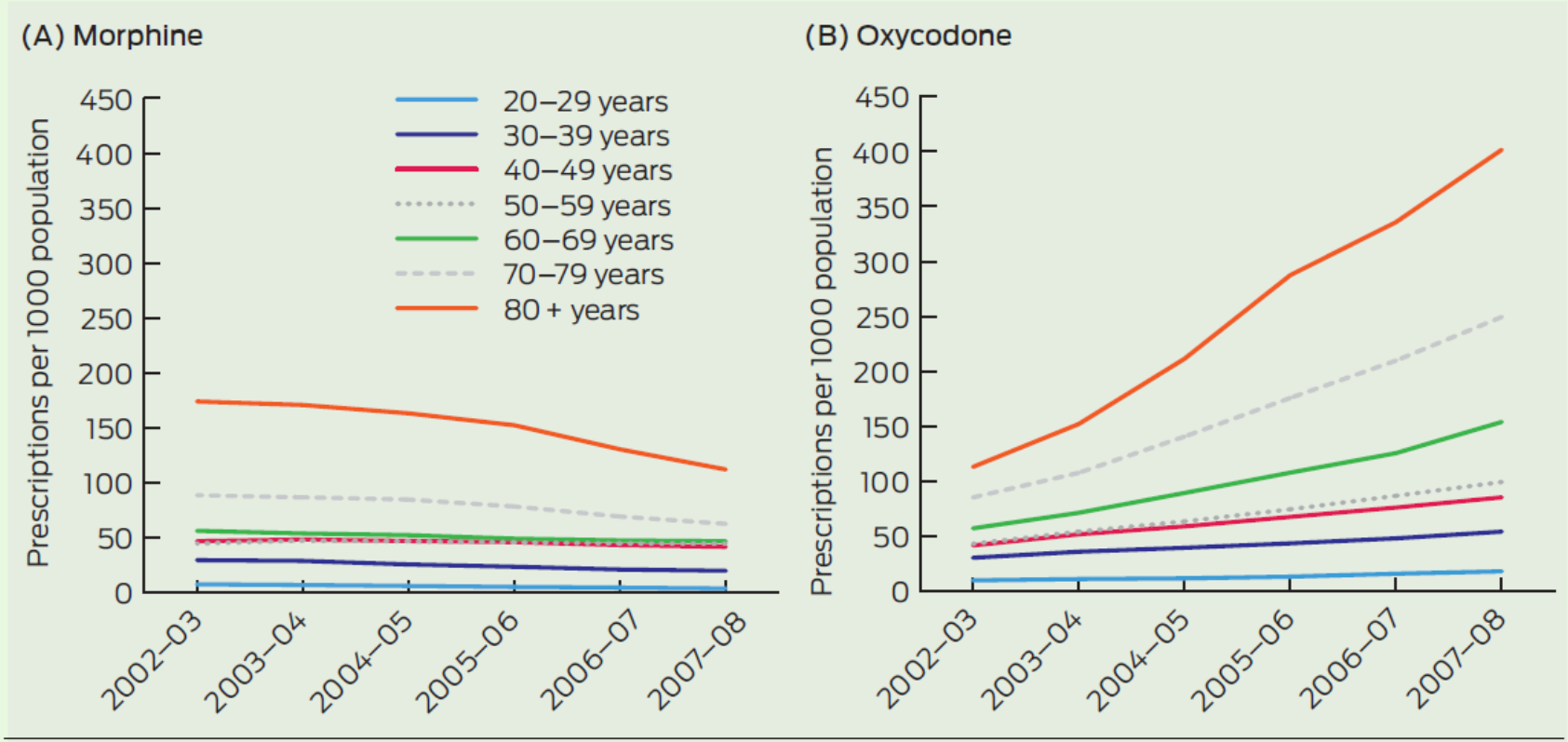
What do we know about prescription rates of restricted pharmaceutical opioids?



NDS Wholesale Data

Where are these prescriptions going?

1 Prescriptions for morphine* and oxycodone† dispensed on the Pharmaceutical Benefits Scheme in Australia from 2002 to 2008, per thousand population, by 10-year age group‡

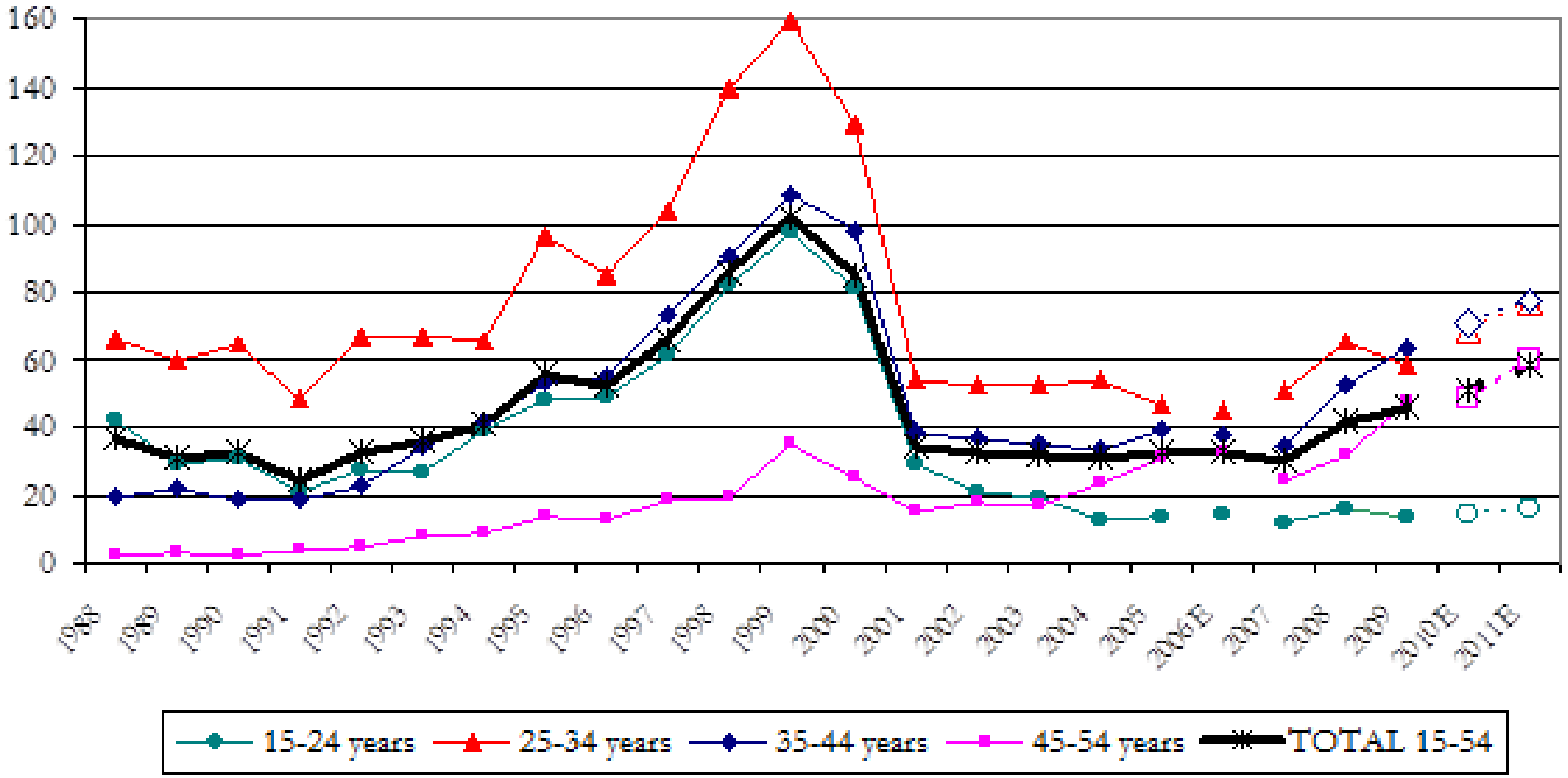


* Includes 10 mg, 20 mg and 30 mg immediate-release tablets; 5 mg, 10 mg, 15 mg, 30 mg, 60 mg, 100 mg and 200 mg controlled-release tablets; 30 mg, 60 mg, 90 mg and 120 mg controlled-release capsules; and 10 mg, 20 mg, 50 mg and 100 mg sustained-release capsules. † Includes 5 mg, 10 mg, 20 mg, 40 mg and 80 mg controlled release tablets and 5 mg, 10 mg, and 20 mg capsules. ‡ Data obtained from the Drug Utilisation Sub-Committee of the Pharmaceutical Benefits Advisory Committee. ◆

Roxburgh et al, 2011

Prescription of opioid analgesics and related harms in Australia

Rate of deaths due to opioids per million persons, Australia 1988-2009



Roxburgh & Burns, 2013

[mandatory image relating to balance]

Pain & Policy Studies Group Statement

Table 2: The Central Principle of Balance

The ***Central Principle of Balance*** represents a dual obligation of governments to establish a system of controls to prevent abuse, trafficking, and diversion of narcotic drugs while, at the same time, ensuring their medical availability.

Medical Availability

- While opioid analgesics are controlled drugs, they are also essential drugs and are absolutely necessary for the relief of pain.
- Opioid analgesics should be accessible to all patients who need them for relief of pain.
- Governments must take steps to ensure the adequate availability of opioids for medical and scientific purposes, including:
  - empowering healthcare practitioners to provide opioids in the course of professional practice,
  - allowing them to prescribe, dispense and administer according to the individual medical needs of patients, and
  - ensuring that a sufficient supply of opioids is available to meet medical demand.

Drug Control

- When misused, opioids pose a threat to society.
- A system of controls is necessary to prevent abuse, trafficking, and diversion, but the system of controls is not intended to diminish the medical usefulness of opioids, nor interfere in their legitimate medical uses and patient care.

Adapted from Pain & Policy Studies Group. *Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation (CY 2012).* University of Wisconsin Carbone Cancer Center. Madison, WI; 2013.

Evidence: Strong for acute pain; severe cancer pain

Evidence: Weak for chronic non-cancer pain: only strong opioids > placebo for pain, ~1/3 reduction in pain, limited improvements to function, ~1/3 drop out

Regulatory Systems Differ Across Aus

	TAS	NSW	VIC
Drugs requiring authority	S8s , (S8 + alpraz)	Hydromorphone, injectables	S8s
Grace period	2 months	2 months	8 weeks
Declared drug dependent pts	Immediate authority	Immediate authority	Immediate authority
Information considered	Clinical indication, other drugs, dose, medication contract, specialist review	Diagnosis, drug type, *current* drug dependence	Clinical indication, treatment plan, specialist review if higher than recommended, notification history
Pharmacy dispensing data	Immediate	~monthly	~monthly

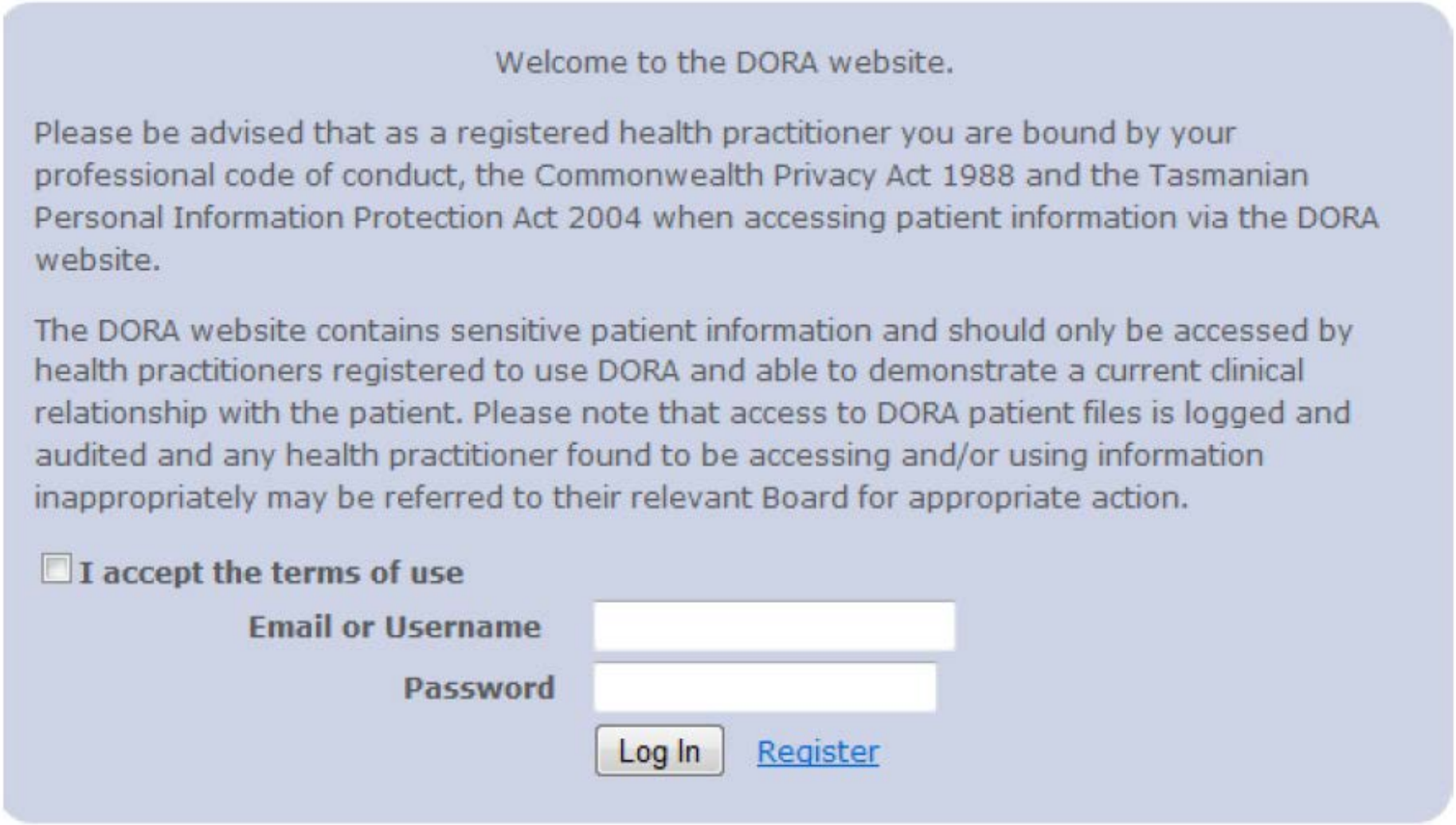
Electronic Recording and Reporting of Controlled Drugs (ERRCD)

- Drugs and Poisons Information System (DAPIS)
  - DAPIS Online Remote Access (DORA)
- National:
  - Commonwealth government is coordinating progress
  - Funding under Fifth Community Pharmacy agreement (2010) until June 2015 ($5M)
    - 2012, after open process, TAS system chosen as model
  - Many issues (legislation, integration, processes) need to be worked through in each jurisdiction (and then need to be consistent nationally)

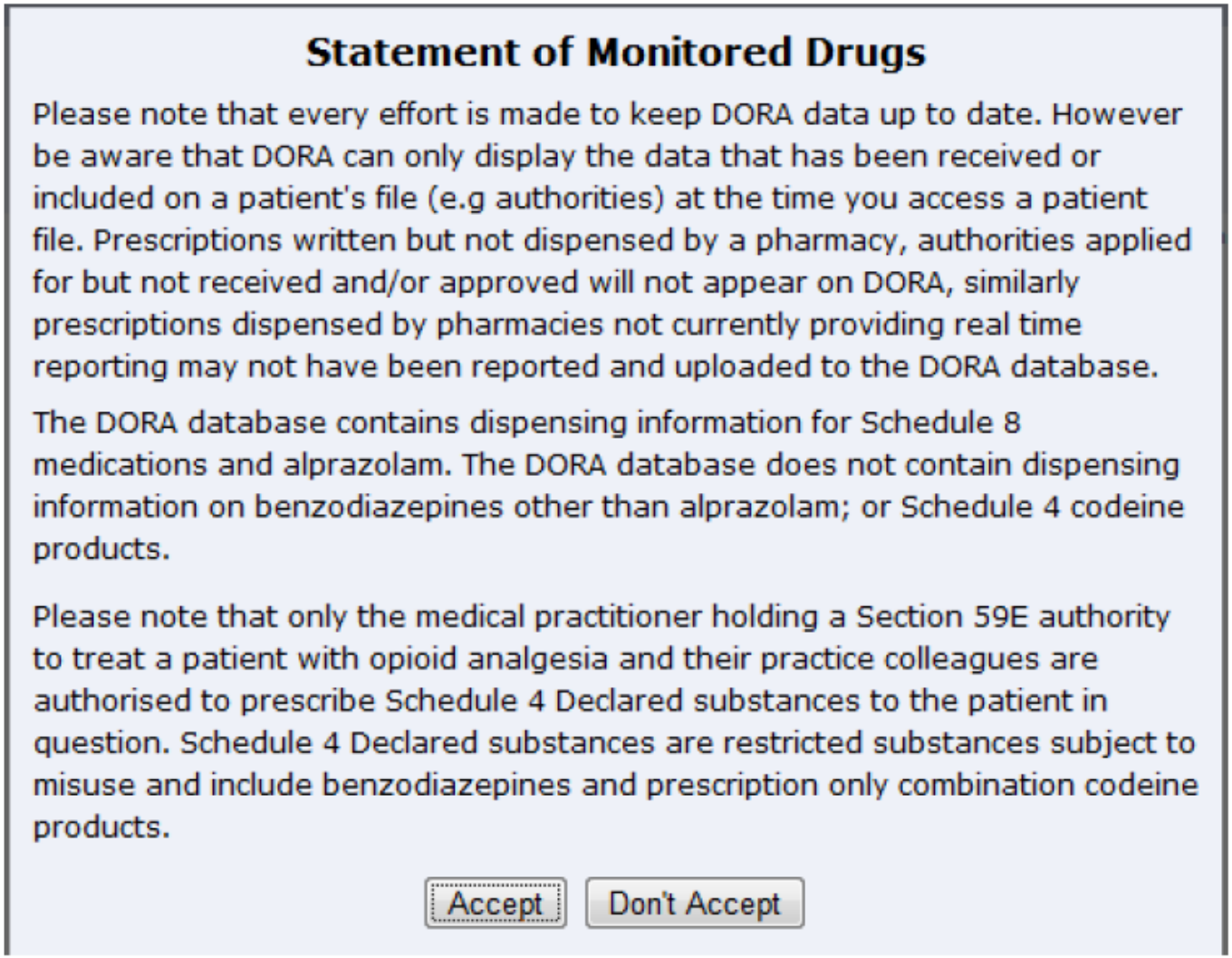
Key Aspects of ERRCD

- All S8 medications monitored
  - dispensing collected immediately (replaces paper systems)
  - Controlled Drug Electronic Register (CDER) integrated with pharmacy dispensing software
- Data about patient available to
  - Prescribers, pharmacists, regulators (PSB)
  - Complies with "Australian Government Protective Security Policy Framework" for security of personal health data
- Data includes
  - Name / dob /
  - Details on dispensed medications (what, when made, when picked up etc)
- Not an 'opt-in' system
- Actively flags alerts (received by PSB) that can be tailored to the jurisdiction context that might suggest 'misuse' or forgery etc

DORA: entirely browser-based system



DORA: What is monitored



Statement of Monitored Drugs

Please note that every effort is made to keep DORA data up to date. However be aware that DORA can only display the data that has been received or included on a patient's file (e.g authorities) at the time you access a patient file. Prescriptions written but not dispensed by a pharmacy, authorities applied for but not received and/or approved will not appear on DORA, similarly prescriptions dispensed by pharmacies not currently providing real time reporting may not have been reported and uploaded to the DORA database.

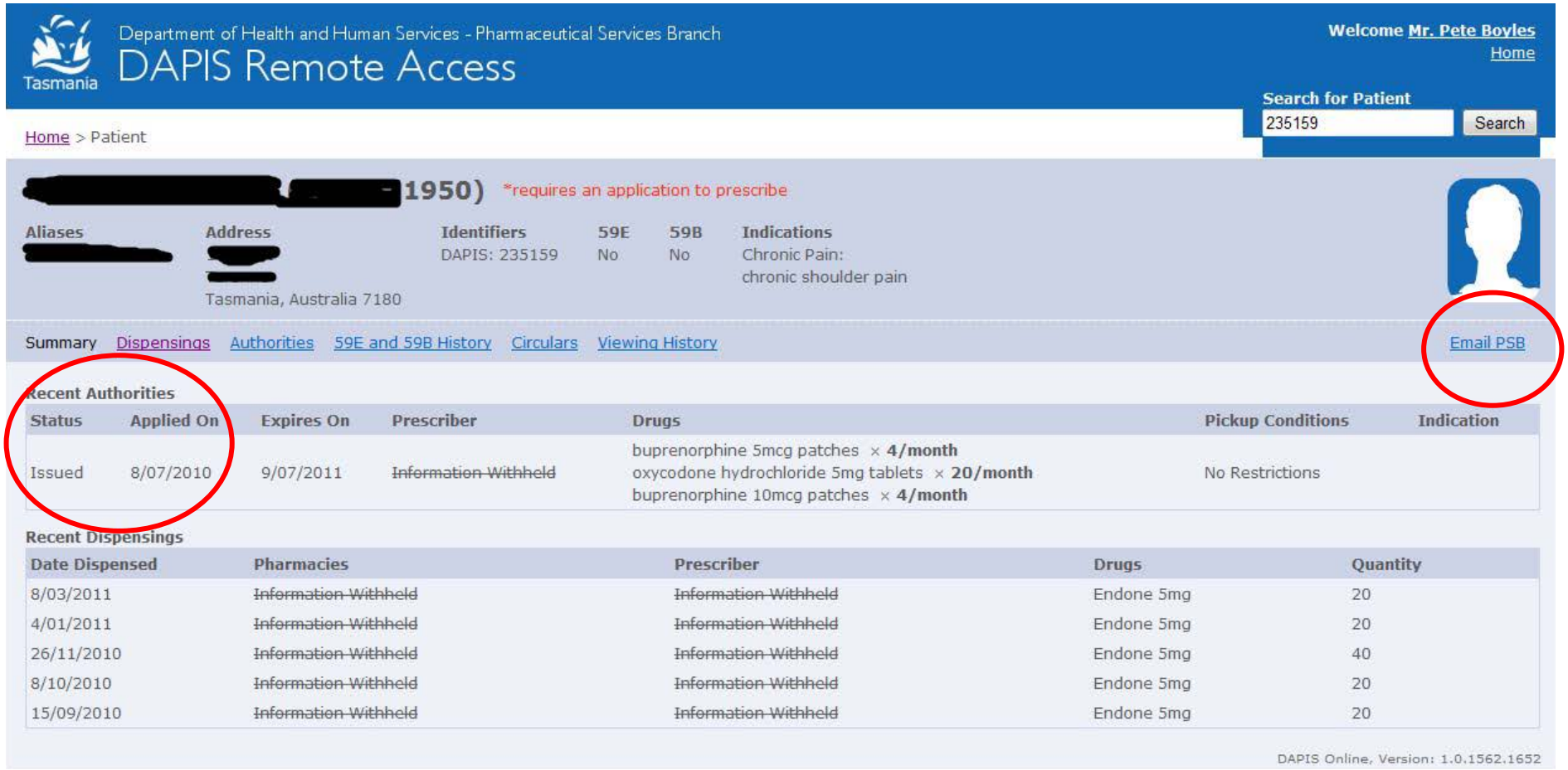
The DORA database contains dispensing information for Schedule 8 medications and alprazolam. The DORA database does not contain dispensing information on benzodiazepines other than alprazolam; or Schedule 4 codeine products.

Please note that only the medical practitioner holding a Section 59E authority to treat a patient with opioid analgesia and their practice colleagues are authorised to prescribe Schedule 4 Declared substances to the patient in question. Schedule 4 Declared substances are restricted substances subject to misuse and include benzodiazepines and prescription only combination codeine products.

Accept Don't Accept

Schedule 4 includes
Antidepressants
Antipsychotics
Benzodiazepines
Tramadol
Panadol forte et al

DORA: Client Information Page



?is this person underdosing?

“requires an application to prescribe”

- Poisons act: “drug seeking behaviour”
- For the purposes of this Act, a person is taken to exhibit drug-seeking behaviour in respect of a drug of dependence if there is reason to believe that –
  - (a) he or she is seeking to obtain a drug of dependence for the purpose of selling or supplying it to another person; or
  - (b) he or she is seeking to obtain a drug of dependence for a non-medical purpose; or
  - (c) as a result of the administration to him or her of the drug, he or she exhibits –
    - (i) impaired ability to manage properly the use of any such drug; or
    - (ii) behaviour which suggests such impaired ability; or
  - (d) failure to obtain drugs of dependence for a non-medical purpose is likely to cause the person to exhibit signs of mental or physical distress or disorder.

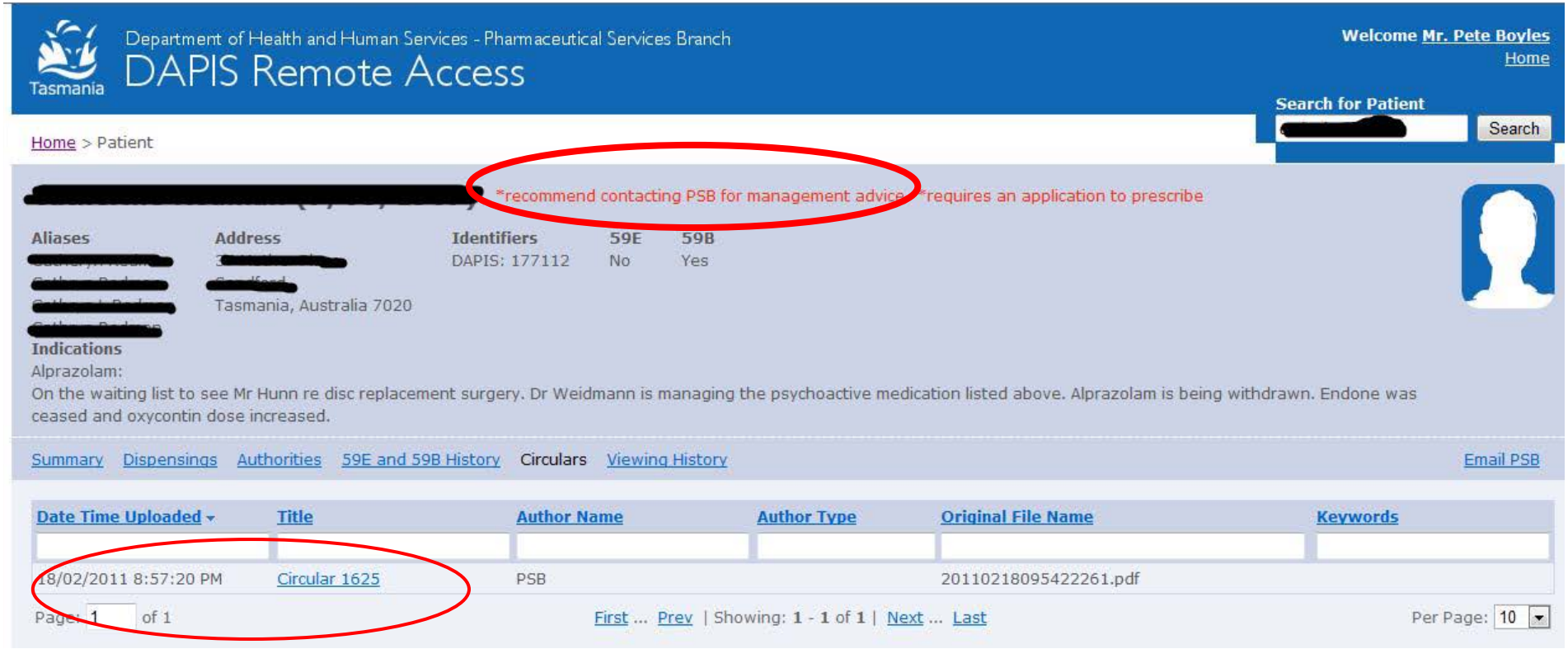
This does not expire

"Indicators of drug seeking"

- seeing multiple doctors for treatment of the same condition;
- having a history of obtaining drugs on the street;
- having visible track marks from injecting;
- alleging lost or stolen prescriptions;
- coming in early to collect their prescription; and/or
- trying to escalate the amount of drugs prescribed.

If there are any signs of drug seeking behaviour in a patient seeking a notifiable restricted substance or narcotic substance, then there is a <u>mandatory requirement</u> under s 59B that the practitioner notify PSB

What happens if declared ‘drug seeking’ under act and treatment is indicated?



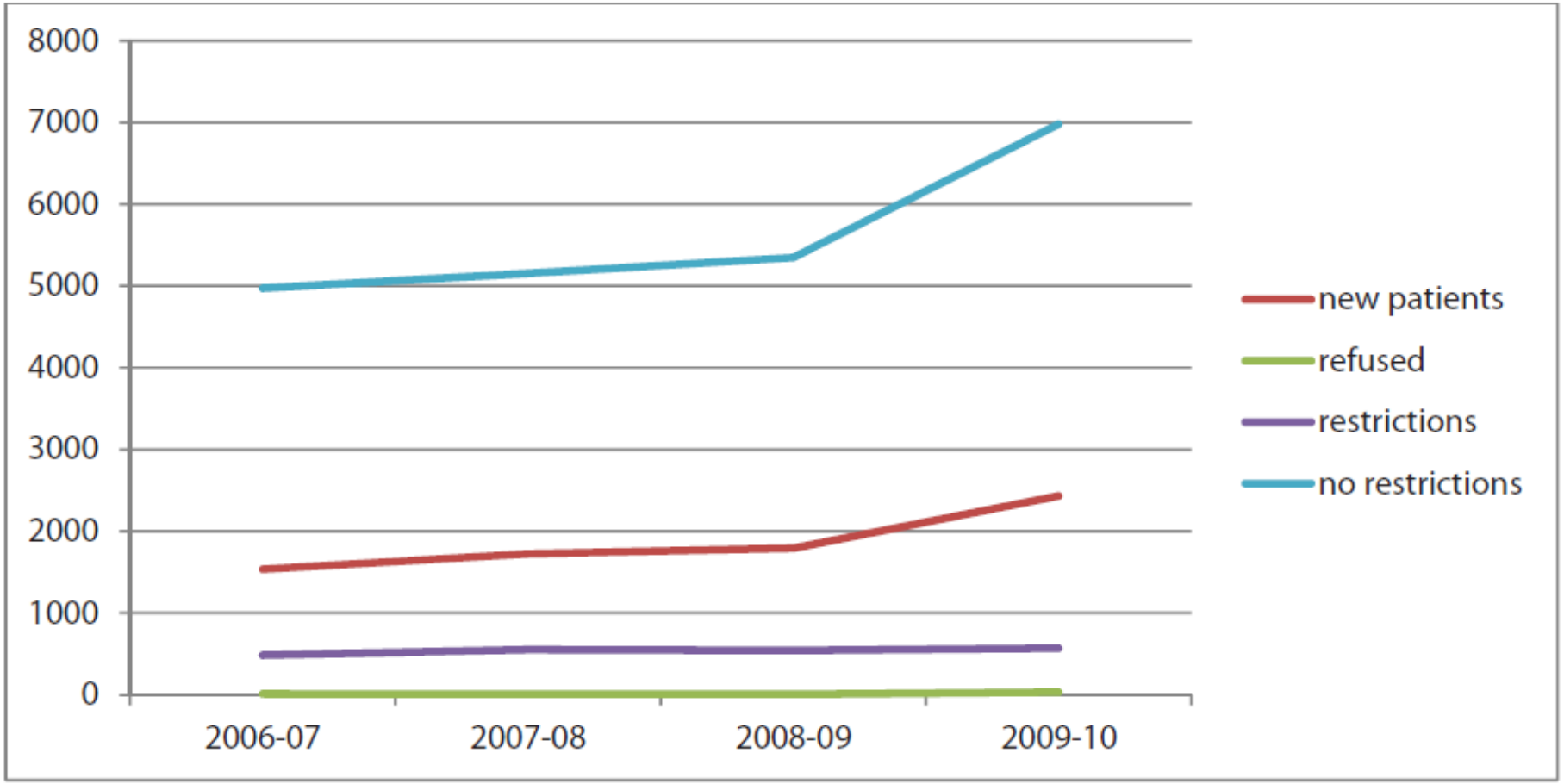
Authority IS possible – typically with ‘limited approval’ initially – and will require submission of a management plan from either an addiction medicine specialist or a pain specialist before it will be approved

DORA: Example of authority conditions

Chronic Pain	Approved	18/03/2011	18/08/2012	Creds R Bogus	morphine sulphate 100mg SR capsules × **2/day**	**This authority is conditional on the following:** • **That the prescription is posted to the one nominated pharmacy** • **This pharmacy should remain the same for the duration of the authority and** • **The medication is dispensed to the patient on a daily basis with all of the doses taken under pharmacist supervision.** • **Take-away doses may be dispensed for days when the pharmacy is closed.** **Please note: if the patient's consumption has previously been erratic, overdose cannot be ruled out.**	Chronic low back pain
Alprazolam	Expired	11/03/2010	11/09/2010	~~Information Withheld~~	alprazolam 2mg tablets × **60/month**	No Restrictions	Panic disorder

Typically: restriction rather than refusal

Figure 7: Number of authorities to prescribe issued without restrictions, refused and restricted in Tasmania, DAPIS, 2006-2010



Pharmacists

Date Dispensed	Pharmacy	Prescriber	Drugs	Quantity
24/01/2011	~~Information Withheld~~	~~Information Withheld~~	Fentanyl 1mg/50ml Amp	3
22/01/2011	~~Information Withheld~~	~~Information Withheld~~	Morphine Sulphate 10mg/Ml Amp	10
21/01/2011	~~Information Withheld~~	~~Information Withheld~~	Xanax 0.5mg	50
13/01/2011	~~Information Withheld~~	~~Information Withheld~~	Endone 5mg	20
6/01/2011	~~Information Withheld~~	~~Information Withheld~~	Norspan 5mcg	2
5/01/2011	~~Information Withheld~~	~~Information Withheld~~	MS Contin 30mg	60
5/01/2011	~~Information Withheld~~	~~Information Withheld~~	Kapanol 50mg	20
5/01/2011	~~Information Withheld~~	~~Information Withheld~~	Norspan 20mcg	2
4/01/2011	~~Information Withheld~~	~~Information Withheld~~	Durogesic 25mcg	5
4/01/2011	~~Information Withheld~~	~~Information Withheld~~	Ordine 2	1

Patient information screen only provides info on authorities and what has been dispensed
Often a delay between prescription and dispensing – pharmacists are a central part of DORA
DORA is directly integrated into dispensing systems (requirement to report to PSB as dispensed), so immediate update
Pharmacists email PSB with reports on individuals → feeds into 'flags' **("recommend contacting PSB for prescribing advice")**

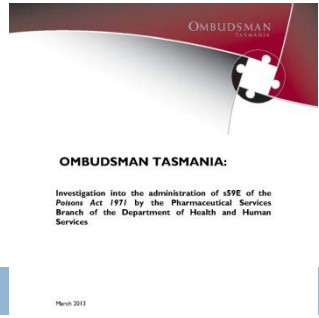
What happens if the decision is to refuse prescription? Or if a person is unwilling to follow dispensing restrictions?

This is a solely supply reduction focussed intervention but also needs consideration of what happens next. Otherwise, what then for the individual?

AIVL/NUAA/CAHMA Submission to National Pharmaceutical Drug Misuse Strategy

"…..AIVL believes it is important to understand that ***such 'misuse' is frequently created by the legal/regulatory system.*** *That is, a system where the very laws and regulations that are designed to manage and monitor access to pharmaceuticals* ***create the circumstances*** *whereby* ***people are unable to get their legitimate needs*** *for pharmaceutical medications* ***met*** *or met adequately, and* ***consequently are forced to resort to self-fashioned treatment programs, self-medication, off-label use, illicit supplies, etc.*** *In short, an increasing number of people end up using pharmaceutical opioids illicitly and/or being labelled as "misusing" pharmaceutical drugs largely because the system is not flexible, responsive or "balanced" enough to meet their "genuine needs". This situation needs to be addressed proactively within the Strategy rather than simply seeking to blame, label and ostracise those who are, through lack of 'legitimate' choices forced outside the system"*

Lessons learnt:
2013 ombudsman's report



- 50 complaints 2007-2011 re: PSB authorisations
  - Medication shift = inadequate relief; increased travel/dispensing cost and restrictions on ability to travel / feeling humiliated
  - PSB has policy of not engaging with clients (only prescribers)
- "In 49 of the complaints received by my Office, the decisions made by PSB had been reasonable."
- Recommendations
  - Natural justice - make available provisions for internal review of authorisation → right of review available to practitioner AND patient
  - Make transparent the decision making process and decisions to prescribers

Implementation

- Tasmania: coming to end of 'pilot phase'
  - Currently: all hospitals, 44 GP practices, 12 community pharmacies (<95% pharmacies directly feed into system)
  - EOFY: aim all GP practices, most pharmacies (depends on dispensing software integration)
- National:
  - Commonwealth government is coordinating progress
  - Many issues (legislation, integration, processes) need to be worked through in each jurisdiction (and then need to be consistent nationally)

Do PMP limit 'abuse' *without* reducing medically appropriate use?

Table 4. The associations between PDMP status and probability of analgesic use by schedule ($n = 834\,489$)

	Opioid analgesic use		
	pCII/pCV-Rx	pCIII/pCV-Rx	pCIV/pCV-Rx
Variables	Odds ratio [99% CI]		
PDMP status			
No PDMP		Reference	
ePDMP	0.76 [0.75, 0.77]	1.19 [1.17, 1.20]	1.08 [1.06, 1.10]
e + pPDMP	0.54 [0.53, 0.55]	1.44 [1.42, 1.46]	0.89 [0.87, 0.91]
	~Schedule 8	~Schedule 4	~OTC

US Medicare-eligible outpatients (2007), n=2,175,012, typically >65

Controlling for age, sex, urbanicity, comorbidities, health service utilisation

1. If you live in an area with a PMP – you have higher odds of receiving analgesic
2. If you live in an area with a PMP – you have lower odds of receiving [S8] and higher odds of [S4]

"I push [compound preparations containing] codeine very hard, and Tramadol. They're schedule 4 drugs so I won't get a rap over the knuckles from the PSB."

Influence of prescription monitoring programs on analgesic utilization by an insured retiree population

Linda Simoni-Wastila[1] and Jingjing Qian[2]*

PHARMACOEPIDEMIOLOGY AND DRUG SAFETY 2012; **21**: 1261–1268

Table 4 Differences in response when suspect diversion or doctor shopping by prescription monitoring program use

Green et al, 2012
N=1385 prescribers

	Typical PMP User Actions vs Typical Non-user Actions (Ref) aOR* [95% CI]
Contact the patients other physician(s) (if known)	0.31 [0.23, 0.41]
Discuss the concerns with the patient	1.16 [0.81, 1.68]
Refer the patient to another provider	1.75 [1.10, 2.80]
Screen the patient for drug abuse	1.93 [1.39, 2.68]
Initiate a treatment agreement/pain contract with the patient	0.92 [0.66, 1.27]
Revisit treatment agreement/pain contract with the patient	1.97 [1.45, 2.67]
Conduct a urine drug screen of the patient	1.82 [1.29, 2.57]
Counsel the patient on potential overdose risk	1.21 [0.83, 1.51]
Refer the patient to substance abuse treatment	1.30 [0.96, 1.75]
Nothing; ignore it	0.09 [0.01, 0.70]
Ask the patient to leave the practice	0.99 [0.67, 1.47]
Notify law enforcement	0.45 [0.21, 0.94]

* Adjusted for age, gender, years practicing, drug abuse screening practices, frequency of prescribing opioids, and state.
aOR [95% CI] = adjusted odds ratio [95% confidence interval].

Green et al, 2013
N=294 pharmacists

Response	Typical PMP user actions vs. typical nonuser actions (reference) aOR (95% CI)
Contact the patient's physician(s) (if known)	0.86 (0.21–3.47)
Discuss the concerns with the patient	0.48 (0.25–0.92)[a]
Refer the patient back to provider	1.50 (0.79–2.86)
Refuse to fill the prescription	0.63 (0.30–1.30)
State out of stock of the drug	0.27 (0.12–0.60)[a]
Counsel the patient on potential overdose risk	0.59 (0.27–1.27)
Refer the patient to substance abuse treatment	1.29 (0.25–6.53)
Ask the patient to leave the pharmacy	0.46 (0.17–1.29)
Notify law enforcement	0.81 (0.33–2.01)

Abbreviations used: aOR, adjusted odds ratio; PMP, prescription monitoring program.
Models are adjusted for age, gender, years practicing pharmacy, drug abuse screening practices, frequency of dispensing opioids, and state.

How Does Use of a Prescription Monitoring Program Change Medical Practice?

Pain Medicine 2012; 13: 1314–1323
Wiley Periodicals, Inc.

What do emergency doctors do?

- UToledo Medical Centre ED
  - ED patients with painful (non-acute) conditions (n=179)
  - Clinical evaluation
  - Provision of PMP data
    - Clinical management change in 41% cases
      - Of these 61% reduced or no opioid
      - Remainder increased opioid given history
- Tasmanian experience anecdotally: time to decision much faster

A Statewide Prescription Monitoring Program Affects Emergency Department Prescribing Behaviors

David F. Baehren, MD, Catherine A. Marco, MD, Danna E. Droz, RPh, JD, Sameer Sinha, BS, E. Megan Callan, BA, Peter Akpunonu, BS

What is the consumer experience?

Random sample of Medicaid participants, n=1279, Kentucky
~90% of people unaffected by the system

Table 3. *KASPER Report prevented prescription from a provider (logistic regressio*

	Odds Ratio
Chronic Pain Diagnosis (Non-cancer)**	2.566
Cancer Diagnosis	0.989
Age 18 to 24	0.769
Age 25 to 34	0.850
Age 35 to 44	0.718
Age 45 to 54	0.621
Age 55 to 64	1.228
High School Graduate	0.856
Race (White)	2.117
Hispanic	1.534
Rural**	0.423
Female	2.425

Table 4. *KASPER Report prevented prescription filled at a pharmacy (logistic re*

	Odds Ratio
Chronic Pain Diagnosis (Non-cancer)	1.352
Cancer Diagnosis	1.231
Age 18 to 24	0.884
Age 25 to 34	1.801
Age 35 to 44	1.675
Age 45 to 54	1.221
Age 55 to 64	2.954
High School Graduate	0.988
Race (White)	1.472
Hispanic**	8.121
Rural**	0.416
Female	1.772

Consumer/Patient Encounters with Prescription Drug Monitoring Programs: Evidence from a Medicaid Population

Amie Goodin, MPP, Karen Blumenschein, PharmD, Patricia Rippetoe Freeman, PhD, and Jeffery Talbert, PhD

Pain Physician 2012; 15:ES169-ES175

Information alone isn't enough

- Good clinical practice is the fundamental key!
  - Enhanced training for evidence based treatment
  - Use of treatment contracts, UP, "triple 5"
  - Integration of these processes in the authorisation process, with structured templates
- Feedback to prescribers
  - Feedback about their rates of prescription against normative data
  - QUM training for opioid prescribing for prescribers engaging in 'unsafe' or 'inappropriate' prescribing

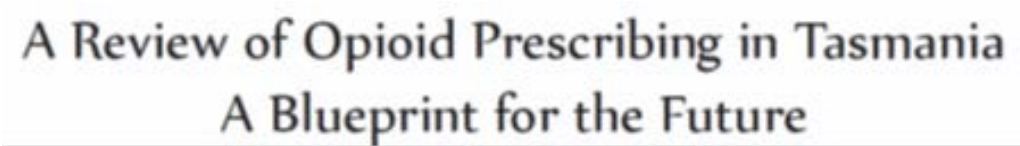


Table 3: Criteria Used to Evaluate State Pain Policies

Positive Criteria: Criteria that identify policy language that may enhance safe and effective pain management

# 1	Controlled substances are recognized as necessary for public health
# 2	Pain management is recognized as part of general healthcare practice
# 3	Medical use of opioids is recognized as legitimate professional practice
# 4	Pain management is encouraged
# 5	Practitioners' concerns about regulatory scrutiny are addressed
# 6	Prescription amount alone is recognized as insufficient to determine legitimacy of prescribing
# 7	Physical dependence or analgesic tolerance are *not* confused with "addiction"
# 8	Other provisions that may enhance pain management
	Category A: Issues related to healthcare professionals
	Category B: Issues related to patients
	Category C: Regulatory or policy issues

Negative Criteria: Criteria that identify policy language that may impede safe and effective pain management

# 9	Opioids are relegated as only a treatment of last resort
#10	Medical use of opioids is implied to be outside legitimate professional practice
#11	Physical dependence or analgesic tolerance are confused with "addiction"
#12	Medical decisions are restricted
	Category A: Restrictions based on patient characteristics
	Category B: Mandated consultation for all patients
	Category C: Restrictions regarding quantity prescribed or dispensed
	Category D: Undue prescription limitations
#13	Length of prescription validity is restricted
#14	Practitioners are subject to undue prescription requirements
#15	Other provisions that may impede pain management
#16	Provisions that are ambiguous
	Category A: Arbitrary standards for legitimate prescribing
	Category B: Unclear intent leading to possible misinterpretation
	Category C: Conflicting or inconsistent policies or provisions

U Wisconsin Pain and Policy Studies Group *(NB: funded by American Cancer Society)*

Summary

- Clear benefits of the system in picking up risky prescribing → adverse events
- Provides clinically important information for establishing treatment plans
- Increased attention to prescription approach and outcomes may lead to increase in use of non-opioid approaches
- Needs careful evaluation for maximising benefits
  - Does RTR shift to poorer management (e.g. S4)?
  - How do pharmacists respond to information?
  - Are there differential responses to marginalised groups?
  - Have we built the required capacity to support people identified with problems or are they being pushed out of medical systems?
- We're still a long way from national roll-out