

DEVELOPING A SCREENING TOOL FOR PRESCRIBED OPIOID DEPENDENCE

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Technical Report

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EXECUTIVE SUMMARY

Aim: Large increases in opioid prescribing have been observed in many countries and are associated with increased in harms including dependence and mortality. One in five people using long-term opioids meet criteria for opioid dependence, and most patients prescribed and dispensed opioids in primary care settings. This makes primary care settings an ideal place to screen for emerging problems with prescribed opioids. An ongoing challenge has been identified in how best to identify problematic use including prescribed opioid (PO) dependence in primary care. The aim of this study was to develop a screening tool for PO dependence, developed for use in primary care settings (general practitioner and community pharmacy screening).

Methods: We used data from The Prescribed Opioids IN Treatment (POINT) Cohort to develop an initial set of questions that were correlated with meeting criteria for prescribed opioid dependence as assessed with a gold standard diagnostic interview (the CIDI). We then used a range of analyses techniques (exploratory and confirmatory factor analyses) to identify combinations of questions that worked together to most effectively identify those who were most likely to be opioid dependent, as determined with the CIDI. We removed questions that didn't work well with other questions at identifying dependence (poor fit), those that were very similar to existing questions that worked well, where few people endorse the answer (rarity) and where wording that was obviously related to dependence, as consultation with primary care providers revealed would be a barrier to use in a primary care setting. Once a final set of questions was identified, we used receiver operator curves to determine the best cut-off score to correctly identify opioid dependence. Finally, we conducted interviews with healthcare professionals (n = 10) and consumers (n = 5) to determine if the wording in the final tool was acceptable, and to identify the best way to introduce the questions to patients, and to fit screening procedures into existing practice.

Results: We developed a four-item scale with a cut-off of score of 2 that had 77% sensitivity and 77% specificity at identifying those that met opioid dependence (as assessed with a CIDI diagnostic interview). The individual questions, and the 4-item screening tool was assessed to have good face-validity and was acceptable to primary healthcare clinicians and patients for administration in primary care settings.

Conclusion: A brief primary care screening tool, validated using a gold standard diagnostic interview was developed. Future research would extend this work by validating tool among people using a broader range of opioids (including weak opioids), and for self-complete administration. Finally, implementation studies are needed to determine how to introduce screening into routine care and to develop optimal clinical pathways where prescription opioid dependence is identified.

1. INTRODUCTION

Large increases in opioid prescribing have been observed in many countries including Australia (Berterame et al., 2016). This increase has been associated with dramatic increases in harms including dependence, morbidity and mortality (Bohnert et al., 2011, Fischer et al., 2013, Roxburgh et al., 2011). Increasing numbers of people are seeking treatment for dependence to pharmaceutical opioids (Nielsen et al., 2015). However, the growth in treatment represents only a fraction of the estimated number of people who experience problematic pharmaceutical opioid (PO) use.

An estimated 750 000 people in Australia (a quarter of the 3 million Australians prescribed opioids annually) are using opioids long- term (Drug utilisation sub-committee (DUSC), 2014, Rogers et al., 2013). One in five people using long-term opioids, or an estimated 150 000 Australians meet the criteria for substance use disorder, with around half of those meeting diagnostic criteria for PO dependence (Degenhardt et al., 2015). This represents a population comparable in size to estimates for the population of heroin dependent people at the peak of the 'heroin epidemic' (Law et al., 2001). Mortality from pharmaceutical opioids exceeds that from heroin by 200% (Roxburgh, 2015), yet little focus has been placed on changing policy and practice to respond to the needs of people dependent on PO. Those people entering traditional treatment services are limited largely to those that inject opioids and have a history of heroin use (Nielsen et al., 2011). As such, it is now critical to reach those at risk who do not seek help. The first step is to be able to identify those developing use disorders with pharmaceutical opioids.

A number of screening tools exist for opioid dependence, though none of these have been validated specifically for prescribed opioid dependence, and many are worded with a focus on illicit opioid use and are not appropriate for use in primary care for patients with chronic pain. As such, there is an identified need for screening tools to help identify those that may be developing dependence with prescribed opioids.

The aim of this study was to develop a screening tool for prescription opioid dependence, developed specifically for use in primary care settings (general practitioner and community pharmacy screening).

2. METHODS

2.1 Participants

Data were used from an existing cohort of patients prescribed strong opioids for chronic pain, the Pain and Opioids IN Treatment (POINT) cohort. Participants in the POINT cohort (n=1514) were patients with chronic pain who were prescribed strong opioids for at least 6 weeks at baseline and were recruited through community pharmacies in Australia. Of the 2,091 participants assessed for eligibility, 90% (n=1873) were eligible and 1514 completed the baseline interview (n=359 refused after being deemed eligible and 74 were unable to be contacted). Full details of the recruitment methods are published elsewhere (Campbell et al., 2014, Campbell et al., 2015).

At baseline, the cohort was 44% male (IQR 42-47) with a median age of 58 years (IQR 48-67). Just under half were unemployed (49%) and a further 31% had retired from work. Just under two-thirds (64%) reported that their employment status had changed due to their pain condition. Participants reported having lived with chronic pain for a median of 10 years (IQR 4.5-20) and had been prescribed a strong opioid for a median of four years (IQR 1.5-10) at baseline. Median OME at baseline was 75 (IQR 36-150).

This study used existing data from the 2-year wave of the cohort. Interviews were conducted with 1278 participants (84% of the baseline cohort) the 2-year timepoint. At the 2-year timepoint participants were a median of 59 years old (IQR 50-69) and 43% were male (IQR 41-46).

The study was approved by the Human Research Ethics Committee of the University of New South Wales (HREC reference: #HC12149 and #HC16916).

2.2 Instruments

Individual items considered for the screening tool were selected from the 2-year interview from the POINT cohort study. Individual measures were identified from the following scales. The full list of the potential questions examined is included in appendix A.

Opioid Related Behaviours in Treatment scale (ORBIT): The Opioid Related Behaviours in Treatment Scale (ORBIT), is a 10-item measure of aberrant behaviours such as doctor shopping, diversion and other examples of unsanctioned use of medications in the three months prior (Larance, 2015).

Problems experienced by patients in opioid treatment: the Prescribed Opioid Difficulties Scale (PODS) examines patient concerns and difficulties associated with their opioid medication (Banta-Green et al., 2010). The scale has sixteen items that assess a range of problems and concerns with opioids, including side effects and concerns about use.

Severity of Dependence Scale (SDS): Severity of Dependence Scale (SDS) assesses the severity of dependence to a range of substances (Gossop et al., 1995). The scale was initially developed to assess severity of illicit drug dependence. This study used items that were adapted by the investigators to assess dependence to pharmaceutical opioids.

Opioid dependence: Opioid dependence was assessed using the Composite International Diagnostic Interview 2.0 (CIDI)(Kessler and Ustun, 2004). The CIDI has been used widely in epidemiological studies in many countries (Demyttenaere et al., 2004, Kessler et al., 2007, Seedat et al., 2009, Wang et al., 2007), and has been shown to have excellent interrater reliability(Kessler and Ustun, 2004), test–retest reliability(Kessler and Ustun, 2004), and agreement with clinician diagnoses(Haro et al., 2006).

Recent prescribed medication and substance use: Participants were asked about current prescribed medications, with examples being given for each class of medications examined. Question also explored if participants had self-regulated their opioid use (e.g. increased or decreased dose). Participants were also asked about if they had used a range of substances in the past 12 months including nicotine and cannabis.

Opioid dose: Daily oral morphine equivalent (OME) doses for the opioids taken by the cohort were estimated using conversion units established through review and synthesis of a range of clinical guidelines (Nielsen et al., 2016). This was based on opioid use recorded in the one-week medication diary.

Adverse Events: Participants were asked about side effects they may have experienced their opioid medication (e.g. nausea, vomiting, drowsiness and fatigue).

Pain Self Efficacy Questionnaire (PSEQ): Pain self-efficacy relates to a person's beliefs about the extent to which they can carry out daily activities, even in the presence of pain. The Pain Self-Efficacy Questionnaire (PSEQ) is a 10-item scale to assess pain self-efficacy (Nicholas, 2007, Nicholas et al., 2008).

Alcohol use: The Alcohol Use Disorders Identification Test (AUDIT) is a 10-item screening tool developed by the World Health Organization (WHO) to assess alcohol consumption, drinking behaviours, and alcohol-related problems (Mattick, 2004, Saunders et al., 1993).

2.3. Data analyses for screening tool development

The POINT database has over 2000 variables that were explored for inclusion in a screening tool. Initial assessment of the database identified 135 candidate items from the 2-year data set that had face validity and were considered for potential inclusion.

The reference standard against which individual items for the screening tool was the ICD-11 criteria for opioid dependence. This was chosen based on recent analyses indicated that it may be optimal for use with prescribed opioids (Degenhardt et al., 2015).

We conducted univariate analyses on this initial set of initial possible items, reducing the number of items to 67 that were associated with prescription opioid dependence as per the ICD-11 criteria when examined individually. Where items were significantly associated ($p < 0.05$) they were then included in the subsequent analyses. Items that were not significantly associated with dependence were removed from further analyses at this stage.

This reduced set of 67 items that were significant at the univariate level were then examined using exploratory and confirmatory factor analyses to explore underlying structure of the items and identify 4-5 items with the best fit and predictive ability to form the final tool for further validation (See Appendix A). Items were removed for poor fit, redundancy, rarity or wording that was either obviously related to dependence (which consultation with primary care providers revealed would be a barrier to asking in a primary care setting) or otherwise inappropriate for a primary care setting.

ROC curves were used to determine the best cut-off with respect to sensitivity and specificity.

2.4 Consultation

We consulted with healthcare professionals ($n = 10$) and consumers ($n = 5$) to determine if the wording in the final tool was acceptable and identify the best way to introduce the questions to patients, and to fit screening procedures into existing practice.

3. RESULTS

3.1 Identifying initial items

Appendix A shows the reduction from the initial items 67 that were associated with dependence in Round 1, to the final five items in Wave 5. Two possible 4-question combinations were identified from five final items. Table 1 shows the proportion of the sample that responded positively to each item, and the two possible combinations of questions.

Table 1. Five final items

Item	Base rates	Option A	Option B
(In the last 3 months) I have used my opioid medication for other purposes, for example to help me sleep or to help with stress or worry (do not count times when you took opioids at bedtime so that you would not be in pain)	4.10%	Y	
Used more medication than prescribed in times of worse pain? This includes as required medication but in greater amounts than prescribed.	27.70%		Y
(In the past 2 weeks) Opiate medicine have caused me to lose interest in my usual activities	15.70%	Y	Y
In the past 2 weeks) Opiate medicines have caused me to feel slowed down, sluggish or sedated.	31.90%	Y	Y
Did you worry about your use of pharmaceutical opioids?	29.70%	Y	Y

The final four-question tool chosen was Option B, chosen due to having the best predictive ability to identify prescription opioid dependence (See Appendix B), and having preferred wording consultation with experts in the field.

3.2 Consultation

We conducted 15 individual interviews to explore implementation issues and finalise items in the tool based on face validity and feedback from health professionals and people with lived experience. Open ended semi-structured interviews were conducted with ten pharmacists and five people with lived-experience. In summary, this consultation revealed:

- Screening for problems with opioids was not a part of standard practice for the pharmacist we interviewed, but that pharmacists felt that they had a clear role to play in screening and were interested in new ways to identify where patients were having problems

- Structured ways to collect information from patients was felt to be of value, but they need to be quick to administer.
- Having patients self-complete the questions, and the use of technology to facilitate screening would assist with implementation as there are considerable time pressures in the pharmacy setting.
- Wording of items was acceptable to health care professionals and consumers and 'not too threatening', with the individual items and the tool being something that pharmacists would feel comfortable asking, and that patients would be willing to be asked in a primary care setting.
- The way in which the tool was introduced is important. Non-judgemental communication is critical. How the information was presented, and the pharmacist-patient relationship may affect the willingness to complete and the honesty of responses. Framing dependence as a side effect of the medication rather than the fault of the patient was described as an important strategy by one consumer.
- Pharmacists and patients felt that a) universal screening would be important so that patients did not feel 'singled out', and b) there are low levels of awareness that opioids can lead to dependence
- Pharmacists felt most patients would be willing to complete a screening tool, and consumers indicated that they would be willing to be asked the questions presented to them.
- Reimbursement of pharmacists' time for providing extended services is important in how feasible it is to introduce new services.
- Pharmacist felt there was value in a refresher course to cover issues of dependence to prescribed opioids, with many indicating that they would like further training.
- Consumers felt that when providing feedback on the results, using specific terms such as 'dependence' or 'over-reliance' on medication would be acceptable.

3.3 Final versions of the screening tool

The final version of the tool are provided in Appendix B. The patient version is formatted to remove scoring for the individual items and cut-off score.

4. CONCLUSIONS

Using existing data, we were able to develop a four-item screening tool that can identify those at risk of prescribed opioid dependence. Consumer and healthcare professional consultation

determined that the tool is acceptable and appropriate for use in community pharmacy and GP settings.

Strengths of the tool include the use of data from a well described community sample of patients prescribed opioids for chronic pain, and validation against a gold standard diagnostic interview (the CIDI) administered by trained researchers. Consultation determined that the wording had face validity and was acceptable to end-users.

There are some limitations to the current work. Firstly, the existing data used was sample of chronic pain patients who were prescribed strong opioids. As such, it isn't clear how findings relate to those less restricted (weaker) opioids (e.g. codeine or tramadol) and those using opioids for acute pain. A further limitation is that POINT cohort data were collected via telephone interviews. To extend the findings of this study and address these limitations further research could validate the tool for online self-complete administration and include a broader sample of people prescribed opioids. Other ways to extend this work at to test the implementation and effectiveness of screening for pharmaceutical opioid dependence in primary care settings. Such studies may establish effective standardised procedures for screening and develop models of care for further assessment and referral where an initial screen indicates likely opioid dependence.

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APPENDIX A. SUMMARY OF ITEM INCLUDED IN INITIAL ANALYSIS AND OUTCOME OVER SUBSEQUENT ROUNDS OF ANALYSES

Variable Label	Question measured	Round 1 (Items associated with ID11-Dependence)	Round 2	Round 3	Round 4- significant misfit in a single factor structure so further reductions required	Round 5
ORBITQ1	I have asked my doctor for an increase in my prescribed dose	y	low loading			
ORBITQ2	I have asked my doctor for an early renewal of my prescription because I had run out early	y	low loading			
ORBITQ3	I have used another person's opioid medication, for example a friend, partner or family member's medication, or bought it from the street	Obvious				
ORBITQ4	I have saved up my opioid medication, just in case I needed it later	y	low loading			
ORBITQ5	I have gone to a different doctor to get more opioid medication and didn't tell my normal doctor about it	y	low loading			
ORBITQ6	I have asked my doctor for another opioid prescription because either I had lost my prescription or medication, had had it stolen or someone else had used it	y	low loading			
ORBITQ7	I have given or sold my prescription or my prescribed medication to someone else	Obvious				
ORBITQ8	I have altered my dose in some other way, for example cutting patches or pills in half, when I was not advised to do so by a healthcare professional	y	low loading			
ORBITQ9	I have taken my opioid medication by a different route than was prescribed, for example by injecting it	Obvious/rarity				
ORBITQ10	I have used my opioid medication for other purposes, for example to help me sleep or to help with stress or worry (do not count times when you took opioids at bedtime so that you would not be in pain)	y	y	Y	Y	RETAINED
AUDIT Score	Total score on the AUDIT (alcohol use)	Y	low loading			
REGULATING OPIOID DOSE1	Used more medication than prescribed in times of worse pain? This includes as required medication but in greater amounts than prescribed.	y	y	y	Y	RETAINED
REGULATING OPIOID DOSE2	Chew pain medication tablets	y	low loading			
REGULATING OPIOID DOSE3	Use less pain meds than prescribed		low loading			
PODS_Q1	Opiate medicine have caused me to lose interest in my usual activities	y	y	y	Y	RETAINED
PODS_Q2	Opiate medicines have caused me to have trouble concentrating or remembering	y	y	y	Redundancy	
PODS_Q3	Opiate medicines have caused me to feel slowed down, sluggish or sedated.	y	y	y	Y	RETAINED
PODS_Q4	Opiate pain medicines have caused me to feel depressed, down or anxious	y	y	y	Redundancy with PODS1 (anhedonia construct)	

PODS_Q5	How often have side effects from opiate medicine interfered with your work, family or social responsibilities?	y	y	y	Relevance	
PODS_Q6	How often did opiate medicine make it hard for you to think clearly?	y	y	y	Redundancy	
PODS_Q7	In the past year, about how many times did opiate medicines make you sleepy or less alert when you were driving, operating machinery or doing something else where you needed to be alert?	y	y	y	Redundancy	
PODS_Q9	I have been preoccupied with or thought constantly about use of opiate pain medicines?	y	y	low loading		
PODS_Q10	In the past year, I have felt that I could not control how much or how often I used opiate medicine	y	y	y	Obvious	
PODS_Q11	In the past year, I have needed to use a higher dose of opiate pain medicine to get the same effect	y	low loading			
PODS_Q12	In the past year, I have worried that I might be dependent on or addicted to opiate pain medicines	y	y	low loading		
PODS_Q13	In the past year, I have wanted to stop using opiate pain medicines or to cut down on the amount of opiate medicines that I use.	y	y	y	Relevance	
PODS_Q14	In the past year, opiate medicines have caused me to have problems with family, friends, or co-workers.	y	y	y	Obvious	
PODS_Q15	In the past year, Family or friends have thought that I may be dependent on or addicted to opiate pain medicines.	Y	y	y	Obvious	
sds1_binary	Did you ever think your use of pharmaceutical opioids was out of control?	Obvious				
sds2_binary	Did the prospect of missing a dose make you very anxious or worried?	y	y	y	Relevance	
sds3_binary	Did you worry about your use of pharmaceutical opioids?	y	y	y	Y	RETAINED
sds4_binary	Did you wish you could stop?	y	y	y	Relevance	
sds5_binary	How difficult would you find it to stop or go without pharmaceutical opioids?	y	low loading			
pseq1	I can enjoy things, despite the pain.	y			PSEQ scale separates from other items	
pseq2	I can do most of the household chores (e.g. tidying-up, washing dishes, etc.), despite the pain.	y			PSEQ scale separates from other items	
pseq3	I can socialise with my friends or family members as often as I used to do, despite the pain.	y			PSEQ scale separates from other items	
pseq4	I can cope with my pain in most situations.	y			PSEQ scale separates from other items	
pseq5	I can do some form of work, despite the pain. ("work" includes housework, paid and unpaid work).	y			PSEQ scale separates from other items	
pseq7	I can cope with my pain without medication.	y			PSEQ scale separates from other items	
pseq8	I can still accomplish most of my goals in life, despite the pain.	y			PSEQ scale separates from other items	
pseq9	I can live a normal lifestyle, despite the pain.	y			PSEQ scale separates from other items	
pseq10	I can gradually become more active, despite the pain.	y			PSEQ scale separates from other items	

Side effect_E	mental cloudiness	y	y	y	Redundancy
Side effect_F	sweating	y	low loading		
Side effect_G	fatigue	y	y	y	Redundancy
Side effect H	drowsiness	y	y	y	Redundancy
CIDI_iu21c	Pharm opioids interfere with responsibilities	y		low loading	
CIDI_iu22c	Pharm opioids cause prob with family	y	y	y	Obvious
CIDI_iu23c	Pharm opioids continue use problems	y	Obvious		
CIDI_iu24c	Pharm opioids under the influence drive	y	y	low loading	
CIDI_iu31c	Pharm opioids desire to use	y	y	y	Obvious
CIDI_iu32c	Pharm opioids needed more	y	y	low loading	
CIDI_iu33c	Pharm opioids withdrawal	y	y	y	Obvious
CIDI_iu34c	Pharm opioid withdrawal avoidance	Obvious			
CIDI_iu35c	Pharm opioids more than intended	y	y	y	Redundancy
CIDI_iu36c	Pharm opioids more frequently than intended				Redundant with moreint
CIDI_iu37c	Pharm opioids cut down	y	y	y	obvious
CIDI_iu38c	Pharm opioids recovering	y	y	y	obvious
CIDI_iu39c	Pharm opioid gave up important activities	y	y	y	relevance
Cannabis12m	Past 12 month cannabis use	Y	low loading		
Nicotine12m	Past 12 month tobacco use	Y	low loading		
Non-medPO12m	Past 12 month non med pharmaceutical opioid use	Y	y		obvious, low loading and haywood case
OME_200	Opioid dose over 200mg of morphine equivalent	y	low loading		
BZD	Taken a benzodiazepine in the last week	y	low loading		

Low loading = low loading (<0.5) on unifactorial structure or make low loadings (<0.5) across 1-3 factor structures
Obvious = item sounds too obviously related to dependence for use in screening in primary care context
Relevance = item may be less relevant in chronic pain context (e.g. item may be more related to pain than dependence)
Redundancy = other item better captured this domain, or had preferred wording for a community setting;

APPENDIX B. PATIENT AND HEALTH CARE PROFESSIONAL VERSIONS OF THE OPIOID DEPENDENCE SCREENING TOOL

Opioid Use and Side Effects

Please indicate how often you have been bothered by the following problems over the past three months. There are no right or wrong answers. Do not spend too much time on any one statement.

	Not at all	A little	Quite a lot	A great deal
1 In the past three months in times of worse pain did you use more opioid medicines than prescribed? (This includes use of "as required" medicine if used in greater amounts than prescribed)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2 In the past three months did opioid medicines cause you to feel slowed down, sluggish or sedated?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3 In the past three months did opioid medicines cause you to lose interest in your usual activities?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4 In the past three months did you worry about your use of opioid medicines?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Opioid Use and Side Effects

Please indicate how often you have been bothered by the following problems over the past three months. There are no right or wrong answers. Do not spend too much time on any one statement.

	Not at all	A little	Quite a lot	A great deal
1 In the past three months in times of worse pain did you use more opioid medicines than prescribed? (This includes use of "as required" medicine if used in greater amounts than prescribed)	0	1	1	1
2 In the past three months did opioid medicines cause you to feel slowed down, sluggish or sedated?	0	1	1	1
3 In the past three months did opioid medicines cause you to lose interest in your usual activities?	0	1	1	1
4 In the past three months did you worry about your use of opioid medicines?	0	1	1	1

A total score of 2 or more over the four items likely meets criteria for opioid dependence. Further assessment is warranted.

