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Aproximacions a la perspectiva de la persona en tractament de manteniment amb metadona: millora percebuda i satisfacció amb el tractament com a indicadors, i participació en el desenvolupament dels instruments de mesura com a eina

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TESI DOCTORAL

Programes de doctorat:

Models i Anàlisi de la Intervenció Psicològica (1995-2012)

Psicologia Clínica i de la Salut (2012-2016)

Directors:

Dr. Joan Guàrdia i Olmos

Dr. Ioseba Iraurgi Castillo

Dr. José Pérez de los Cobos Peris

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A Imma (*in memoriam*)

A Fina

AGRAÏMENTS

Aquest treball és fruit de l’esforç de moltes persones. Voldria donar les gràcies molt especialment:

a tots els usuaris/pacients i professionals que heu participat en aquests estudis, pel vostre compromís i implicació;

a tots els meus amics, pel vostre suport incondicional i per tolerar una pila d’hores no compartides —furtades— al llarg d’aquest viatge;

a aquells investigadors que amb els seus estudis i publicacions m’han ajudat a construir i sustentar els límits i els continguts d’aquest treball;

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a la meva família, per les facilitats i ànims en aquest procés quasi etern;

als meus directors de tesi, per la vostra confiança i disponibilitat, per la llibertat que m’he pres a l’hora de subvertir els marges i el mètode del projecte original, i per la paciència amb els meus tempos;

a totes les altres persones que heu format part d’aquest trajecte.

When the right thing can only be measured poorly, it tends to cause the wrong thing to be measured, only because it can be measured well. And it is often much worse to have good measurement of the wrong thing —especially when, as is so often the case, the wrong thing will in fact be used as an indicator of the right thing— than to have poor measurements of the right thing.

John W. Tukey (1979)

Ostracized as "outside of the community", drug users are not granted a voice in health policies that affect their well-being; quite simply, because they are defined as "bad people" their perspectives are irrelevant. Without doubt, this insidious pattern of demonization has contributed, needlessly, to continued spread of HIV/AIDS.

Merrill Singer (2006)

There is still a widespread view that clients' views on treatment and change are secondary, may be inaccurate and are of less worth than objective data. That failure to appreciate that the views of participants might offer an alternative, and equally valid, viewpoint on a process which remains somewhat mysterious to us, and about which they are the principal protagonists and therefore, arguably, the chief 'experts', is an indication of the depth of resistance that exists in the treatment field towards taking the patient's view seriously.

Jim Orford (2008)

There is a certain 'teflon effect' in discourses about treatment: users' criticism of treatment is likely to be interpreted as expressions of their deviance or of their habitual 'denial' of their need for treatment, rather than as statements about the quality of treatment. Invariably regarded as striving towards the good, treatment practices tend to become critique resistant, or possibly in need of only minor adjustments. Problems with treatment tend to be attributed to the more likely source of maladjusted users who resist their own good.

Steffen Jöhncke (2009)

The politics and political economy of evidence, also known as data, is not a question of evidence or no evidence. It is rather a question of who has the power to control the definition of evidence, who defines the kinds of materials that count as evidence, who determines what methods best produce the best forms of evidence, whose criteria and standards are used to evaluate quality evidence? The politics of data, the politics of evidence cannot be separated from the ethics of evidence.

Norman K. Denzin (2013)

ÍNDEX

LLISTA DE SIGLES I ACRÒNIMS

AVAD	Anys de vida ajustats per discapacitat
CEEISCAT	Centre d’Estudis Epidemiològics sobre les ITS i SIDA de Catalunya
DSM-IV	*Diagnostic and Statistical Manual of Mental Disorders, fourth edition*
EMCDDA	European Monitoring Centre for Drugs and Drug Addiction
GHQ-28	*General Health Questionnaire – 28*
MBE	Medicina basada en l’evidència
MRCP	Mesures de resultats comunicats pels pacients
OEDT	Observatorio Español de la Droga y las Toxicomanías
PRD	Programes de reducció de danys
PUDVP	Persones usuàries de drogues per via parenteral
QVRS	Qualitat de vida relacionada amb la salut
SIDA	Síndrome d’immunodeficiència humana
TMAO	Tractament de manteniment amb agonistes opioides
TMM	Tractament de manteniment amb metadona
TSQM	*Treatment Satisfaction Questionnaire for Medication*
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNODC	United Nations Office on Drugs and Crime
VIH	Virus de la immunodeficiència humana
VSSS-MT	*Verona Service Satisfaction Scale for Methadone Treatment*
WHO	World Health Organization

RESUM

Els tractaments de manteniment amb metadona (TMM) són un autèntic tractament psicofarmacològic de la dependència d'heroïna i, a la vegada, un element indispensable i fonamental de les polítiques i les intervencions de reducció de danys. L'efectivitat dels TMM ha estat avaluada, quasi de manera exclusiva, mitjançant la utilització d'indicadors anomenats durs. Intentant trencar el motlle d'aquest enfocament tradicional, aquesta tesi pretén contribuir al procés de generar coneixement al voltant de —i amb— la perspectiva de la persona en TMM.

El nucli del treball doctoral està format per sis articles publicats en revistes internacionals, els resultats principals dels quals són: (1) l'avaluació realitzada pel clínic de la millora del pacient en TMM presenta una dèbil concordança amb la realitzada pel pacient mateix; (2) la versió espanyola del *Treatment Satisfaction Questionnaire for Medication* és un instrument breu, genèric i psicomètricament robust per a l'avaluació, de manera multidimensional, de la satisfacció dels pacients en TMM amb la metadona com a medicament; (3) els pacients tractats en centres amb un nombre més gran d'usuaris, que es perceben a si mateixos com a participants en certa mesura actius a l'hora de prendre decisions relatives al tractament i que presenten un menor deteriorament quant a funcionament psicosocial, es mostren més satisfets amb el TMM; (4) les mesures de resultats comunicats pels pacients (MRCP) poden classificar-se, en funció del nivell de reconeixement i incorporació de la perspectiva del pacient en el procés de disseny i desenvolupament de l'instrument, en les quatre categories següents: MRCP generades pels pacients, MRCP centrades en els pacients, MRCP valorades pels pacients i MRCP irrellevants per als pacients; (5) les enquestes de satisfacció dels pacients amb els TMM, tal com s'implementen en l'actualitat, no són una eina útil per a la millora de la qualitat assistencial; (6) una avaluació de resultats que no incorpori instruments rellevants per al pacient pot comportar l'obtenció d'informació incompleta, si no errònia, fet que problematitza qualsevol avaluació dels TMM.

La conclusió principal d'aquesta tesi és que els instruments de mesura de resultats comunicats pels pacients han de dissenyar-se i desenvolupar-se mitjançant metodologies realment participatives. Subsegüentment, l'avaluació de l'efectivitat dels TMM requereix un equilibri entre els indicadors/instruments desenvolupats de manera tradicional i els rellevants per als pacients; si no, difícilment es possibilitarà una avaluació de resultats que incorpori realment la perspectiva del pacient.

ABSTRACT

Methadone maintenance treatment (MMT) is both a specific psychopharmacological treatment of heroin dependence and a core harm-reduction intervention. By breaking the mould of the traditional focus on the so-called hard indicators of MMT effectiveness, the present dissertation makes room for the consideration of the perspectives of methadone-maintained patients.

This dissertation compiles the main findings of six papers: (1) MMT patients' perception of improvement shows low concordance with the clinical staff's perspective; (2) The Spanish version of the Treatment Satisfaction Questionnaire for Medication is a brief, generic, and psychometrically sound instrument to assess satisfaction with methadone as a medication in a multidimensional manner; (3) Patients are more likely to be satisfied with MMT if they come from large centres, perceive themselves as participating to some extent in treatment decisions, and show lower deterioration in social functioning; (4) Patient-reported outcome measures (PROMs) can be classified according to the degree to which they genuinely incorporate and measure patient perspectives. These can be sorted out into four distinct categories: Patient-generated PROMs, Patient-centred PROMs, Patient-valued PROMs, and Patient-irrelevant PROMs; (5) User satisfaction surveys —as currently designed and carried out in MMT centres— do not significantly help improving treatment quality; (6) A lack of patient-relevant outcome measurement instruments can lead to incomplete, if not misleading, information that problematizes any evaluation of MMT.

The main conclusion of this dissertation is that patient-reported outcome measurement instruments should be developed in a truly participatory manner. Subsequently, MMT effectiveness should be evaluated using traditionally-derived and patient-oriented indicators/instruments simultaneously, so as to provide outcomes assessment that genuinely includes the patient perspective.

0.

Consideracions preliminars

L'any 1972, Brown, Bass, Gauvey i Kozel consideraven que «[...] relatively little attention has been paid to the ideas and concerns about the use of methadone maintenance among [...] the addict-clients for whom treatment was developed» (p. 247). Aquesta situació semblava que es mantenia sense gaire canvis vint-i-sis anys després, quan Hunt i Rosenbaum (1998) destacaven que «[...] it is surprising that so little attention has been paid to investigating methadone maintenance clients' view of treatment» (p. 188). Fa pocs mesos, Vanderplasschen, Naert, Vander Laenen i De Maeyer (2015) semblava que confirmaven l'absència de canvis substancials sobre aquesta qüestió: «Although opiate substitution treatment is an evidence-based and widely available intervention for opiate dependent individuals, evaluation studies have primarily focused on objective outcome indicators rather than on clients' perspectives and personal experiences» (p. 272).

Considerant aquests antecedents, especialment en un moment en què les polítiques sanitàries s'omplen la boca de conceptes com ara *satisfacció de l'usuari* i *participació ciutadana*, i les guies de pràctica clínica emfatitzen els valors i les preferències dels pacients a l'hora de prendre decisions, potser no és irrellevant aportar el nostre gra de sorra al procés d'intentar investigar i generar coneixement al voltant de —i amb— la perspectiva de la persona en tractament de manteniment amb metadona.

Aquest treball de tesi no és un projecte independent, sinó l'expressió d'una línia de recerca que, avui, encara continua i té projecció de futur. No obstant això, per ser formalment i acadèmicament dipositada, llegida i defensada com a tesi, aquesta expressió havia de presentar-se com un producte «acabat» i, d'aquesta manera, poder ser comunicable com un moment/text (Montenegro, 2001). Abans de presentar de manera succinta la seva estructura, voldríem, però, explicitar alguns dels esdeveniments o recorreguts i algunes de les decisions que han contribuït a la configuració dels seus límits i continguts.

Un dels eixos fonamentals per a la construcció de l'objecte d'estudi d'aquesta línia de recerca està relacionat amb l'activitat laboral que duc a terme des de fa pràcticament tres decennis, és a dir, amb la meva experiència en l'àmbit de l'abordatge dels trastorns addictius, concretament en el camp dels tractaments de manteniment amb metadona, i amb la meva exposició a aquest àmbit. Aquesta experiència/exposició seria, però, del tot insuficient sense la preocupació per intentar avaluar els resultats de les nostres intervencions en el marc de la pràctica assistencial, és a dir, en condicions de pràctica clínica habitual. Aquesta preocupació per l'avaluació de resultats tampoc no seria, però, suficient sense l'interès per la mirada o la perspectiva de la persona en tractament o, senzillament, sense la curiositat —indispensable per continuar mirant i reflexionant— «de savoir si on peut penser autrement qu'on ne pense et percevoir autrement qu'on ne voit» (Foucault, 1984, p. 14).

Pel que fa a les moltes decisions preses —a la vegada possibilitadores i limitadores de la recerca mateixa—, voldríem igualment, per motius de transparència i rigor, especificar els motius principals i l'abast de la decisió més important, la vinculada amb la metodologia utilitzada majoritàriament en els diferents estudis que componen aquesta tesi —potser no tan majoritàriament des de la incorporació d'un darrer article publicat fa pocs mesos, però sí clarament en la nostra trajectòria de recerca en aquest àmbit. Qualsevol procés de recerca comporta, entre moltes altres i diverses tries, escollir una determinada metodologia, entesa no només com un conjunt de mètodes i tècniques, sinó també com els principis o premisses sobre la naturalesa del coneixement en els quals es fonamenta. El fet d'haver optat en una majoria d'ocasions per la metodologia quantitativa —molt probablement a causa del biaix de la nostra formació en recerca i de la important orientació biomèdica de la pràctica totalitat de línies de recerca en el meu àmbit laboral— no implica ni molt menys que comparteixi una concepció representacionista del coneixement o de la recerca, o que cregui en la possibilitat d'un investigador neutral, lliure de biaixos culturals, socials o experiencials. Ans al contrari, personalment, i tal com han reconegut prèviament altres autors en els seus respectius casos (per exemple, Asún, 2006*a*), quan administro alguna escala dissenyada per mesurar algun constructe —com, per exemple, la satisfacció amb el tractament—, no considero que estic mesurant una realitat «objectiva» i «independent» de l'instrument de mesura mateix. En paraules del mateix autor (Asún, 2006*b*), el sol fet de preguntar genera que la persona enquestada es posi en una situació en què no s'havia trobat amb anterioritat o davant d'alternatives diferents de la manera com abans pensava sobre la qüestió objecte d'estudi. Per exemple, una persona en tractament de manteniment amb metadona potser no s'havia plantejat mai el seu «nivell de satisfacció amb el tractament» o, si més no, no ho havia fet en els termes dels graus o opcions de resposta proposats pel qüestionari. Així doncs, quan administrem un qüestionari estem produint informació i no només recollint-la; és a dir, la realitat que estudiem està sent construïda a la vegada que l'observem (Asún, 2006*b*). De fet, com han remarcat diversos autors (Bassi, 2014; Páramo i Otálvaro, 2006; Reichardt i Cook, 1986; Vannini, 2015), no existeix una connexió o vincle intrínsec entre el positivisme i la metodologia quantitativa, i aquesta metodologia pot basar-se igualment en un paradigma o perspectiva no positivista. És, doncs, aquesta compatibilitat amb els plantejaments no positivistes una de les condicions de possibilitat que també explicaria, en part —en el meu cas, si més no—, el nostre recurs majoritari a la metodologia quantitativa. En qualsevol cas, entenc els productes de la nostra recerca com a coneixements situats (Haraway, 1988) —en la mesura que qualsevol coneixement es produeix des d'una posició determinada des de la qual és possible una certa manera de mirar l'objecte d'estudi— i, per tant, necessàriament parcials.

Cal afegir finalment que, com qualsevol treball de tesi, es tracta d'un treball col·lectiu resultant de la participació —de múltiples maneres— de moltes persones. En coherència amb aquest fet, en els paràgrafs precedents hem preferit utilitzar la primera persona del plural —o bé formes impersonals— i hem reservat la del singular per referir-nos a itineraris específics o posicionaments concrets del doctorand. Parlant d'aspectes vinculats amb la redacció d'aquest text, i permetent-nos un penúltim excurs, a les pàgines següents utilitzarem el terme masculí d'usuari per referir-nos indistintament a l'usuari i la usuària, i l'article masculí —en singular o plural— davant de mots com ara *pacient* o *clínic* per referir-nos indistintament a pacients o clínics de qualsevol gènere, per afavorir la fluïdesa del text —evitant els repetits desdoblaments del gènere gramatical— i sense cap intencionalitat d'incórrer en un ús sexista del llenguatge. Així mateix, tot i que som conscients del fet que les paraules que emprem per referir-nos a les persones en tractament de manteniment amb metadona són metàfores de la nostra manera de concebre-les o representar-les i indicadors de com construïm la nostra relació amb elles (Beresford, 2005*a*; Kelly, Saitz i Wakeman, 2016; McLaughlin, 2009), utilitzarem de manera indistinta els termes *pacient* o *usuari* —a manca d'altres alternatives més apropiades— perquè en el col·lectiu de persones en tractament de manteniment amb metadona —considerem que són els implicats mateixos els qui ho haurien de decidir— no hi ha una preferència marcada per un terme o un altre (a tall d'exemple, esmentem únicament el nom de dues associacions sorgides d'aquest col·lectiu: Asociación de Usuarios en Mantenimiento con Metadona Organizados [AUMMO] i Asociación de Pacientes Dependientes a Opiáceos [APDO]). Com a darrera consideració relativa a la redacció, cal explicitar també que utilitzarem sovint el terme *perspectiva* en singular tot i reconèixer la seva pluralitat (Tutenges, Kolind i Uhl, 2015) —tant en el cas del col·lectiu esmentat com en el dels diferents professionals implicats en els tractaments de manteniment amb metadona—, amb la intenció únicament de facilitar la lectura del text i no des de l'assumpció que es tracta d'una perspectiva unívoca o monolítica.

Com deia prèviament, aquest treball de tesi, presentat per obtenir el títol de doctor en Psicologia per la Universitat de Barcelona, no és un estudi empíric aïllat, sinó la suma d'alguns dels productes d'una línia de recerca desenvolupada durant els darrers quinze anys i escaig —el primer resultat públic de la qual va ser una comunicació escrita presentada a la 10th International Conference on the Reduction of Drug Related Harm (Trujols, Tejero, Duro i Casas, 1999). Aquesta tesi doctoral ha estat elaborada d'acord amb els requisits establerts per la Universitat de Barcelona i la seva Facultat de Psicologia per a la presentació de tesis com a compendi de publicacions, i el nucli del treball doctoral està format pels següents sis articles publicats en revistes científiques internacionals amb impacte reconegut, indexades en les principals bases de dades bibliogràfiques i bibliomètriques:

Trujols, J., Siñol, N., Iraurgi, I., Batlle, F., Guàrdia, J. i Pérez de los Cobos, J. (2011). Patient and clinician's ratings of improvement in methadone-maintained patients: Differing perspectives? *Harm Reduction Journal*, *8*, 23. doi:10.1186/1477-7517-8-23 [FI = 1,258]

Trujols, J., Iraurgi, I., Siñol, N., Portella, M.J., Pérez, V. i Pérez de los Cobos, J. (2012). Satisfaction with methadone as a medication: psychometric properties of the Spanish version of the Treatment Satisfaction Questionnaire for Medication. *Journal of Clinical Psychopharmacology*, *32*, 69-74. doi:10.1097/JCP.0b013e3182401e09 [FI = 3,513]

Trujols, J., Garijo, I., Siñol, N., del Pozo, J., Portella, M.J. i Pérez de los Cobos J. (2012). Patient satisfaction with methadone maintenance treatment: the relevance of participation in treatment and social functioning. *Drug and Alcohol Dependence*, *123*, 41-47. doi:10.1016/j.drugalcdep.2011.10.014 [FI = 3,141]

Trujols, J., Portella, M.J., Iraurgi, I., Campins, M.J., Siñol, N. i Pérez de los Cobos, J. (2013). Patient-reported outcome measures: are they patient-generated, patient-centred or patient-valued? *Journal of Mental Health*, *22*, 555-562. doi:10.3109/09638237.2012.734653 [FI = 1,762]

Trujols, J., Iraurgi, I., Oviedo-Joekes, E. i Guàrdia-Olmos, J. (2014). A critical analysis of user satisfaction surveys in addiction services: opioid maintenance treatment as a representative case study. *Patient Preference and Adherence*, *8*, 107-117. doi:10.2147/PPA.S52060 [FI = 1,676]

Trujols, J., Iraurgi, I., Batlle, F., Duran-Sindreu, S. i Pérez de los Cobos, J. (2015). Towards a genuinely user-centred evaluation of harm reduction and addiction treatment programmes: A further proposal. *International Journal of Drug Policy*, *26*, 1285-1287. doi:10.1016/j.drugpo.2015.08.012 [FI = 3,119]

Si se'm permet una darrera digressió, i com a intent de disculpa pel temps d'espera —dites anònimes, convertides ja en autèntics «clàssics», del tipus «la tesis no se crea ni se destruye... solo se pospone», poden arribar a ser premonitòries— en què he incorregut durant aquest «procés de la tesi», faig meves, salvant totes les distàncies, unes paraules de Jacques Derrida (1990, p. 439):

> «Devrait-on parler d'une époque de la thèse? D'une thèse qui demanderait du temps, beaucoup de temps, ou d'une thèse qui aurait fait son temps? Bref, y a-t-il un temps de la thèse? Et même, devra-t-on parler d'un âge de la thèse ou d'un âge pour la thèse?».

1.

Introducció. Els tractaments de manteniment amb metadona en el marc de les intervencions de reducció de danys

1.1. Consum injectat de drogues, infecció pel VIH i trastorn per consum d'opioides

L'estimació del nombre de persones que arreu del món s'injecten drogues il·legalitzades se situa entre 15 i 16 milions de persones (Gowing et al., 2015; Matthers et al., 2008), de les quals uns 3 milions són seropositives al virus de la immunodeficiència humana (VIH) (Mathers et al., 2008). Així mateix, el nombre de consumidors dependents d'opioides se situa en 15,5 milions (Degenhardt et al., 2014). En funció d'aquestes dades s'estima que, l'any 2010, els trastorns per dependència de substàncies il·legalitzades explicaven 20 milions d'anys de vida ajustats per discapacitat (AVAD) (Degenhardt et al., 2013), és a dir, representaven la pèrdua de 20 milions d'anys de salut plena (els AVAD constitueixen la mesura que s'utilitza habitualment per resumir les conseqüències o càrrega d'una malaltia o trastorn concret, i engloben tant els anys de vida perduts per mortalitat prematura com els anys viscuts amb discapacitat). La dependència d'opioides, anomenada actualment *trastorn per consum d'opioides* (American Psychiatric Association, 2014), era la principal contribuïdora a la càrrega dels diferents trastorns per dependència de substàncies il·legalitzades, pel fet de representar-ne el 46 % (Degenhardt et al., 2013), i una contribuïdora significativa i creixent a la càrrega global de malaltia (0,37 %; Degenhardt et al., 2014). Per la seva banda, i respecte als AVAD atribuïbles al consum de drogues com a factor de risc per a altres malalties, el consum injectat de drogues, com a pràctica de risc per a la infecció pel VIH, explicava 2,1 milions d'AVAD (Degenhardt et al., 2013).

Pel que fa a estimacions més acotades en termes d'àmbits geogràfics, cal destacar un estudi realitzat als EUA que mostra un augment estadísticament significatiu de la prevalença de l'abús i la dependència d'heroïna entre els anys 2002 i 2013 (C. M. Jones, Logan, Gladden i Bohm, 2015). Altres dades especialment remarcables d'aquest estudi són: *a*) la magnitud del canvi (un 90 % entre els períodes 2002-2004 i 2011-2013 i un 36 % entre 2008-2010 i 2011-2013); *b*) l'augment pràcticament paral·lel del nombre de persones mortes per sobredosi relacionada amb el consum d'heroïna; i *c*) el fet que l'augment del consum d'heroïna s'ha produït en pràcticament tots els grups sociodemogràfics i en un context de policonsum d'altres substàncies psicoactives (C. M. Jones, Logan et al., 2015).

Pel que fa a Europa, tant estudis recents (Barrio et al., 2013; Sarasa-Renedo et al., 2015) com els darrers informes de l'European Monitoring Centre for Drugs and Drug Addiction (EMCDDA, 2014, 2015*a*) mostren que les tendències temporals disponibles sobre el consum de drogues per via parenteral no suggereixen cap pauta general, i mostren descensos en alguns països i regions i augments en altres. No obstant això, els resultats indiquen que, a escala global europea, el nombre de persones usuàries de drogues per via parenteral (PUDVP) ha anat disminuint al llarg dels darrers anys en la població admesa a tractament (EMCDDA, 2015*a*; Sarasa-Renedo et al., 2015), una disminució que, en el cas de l'Estat espanyol i pel que fa al nombre de PUDVP que iniciaven el seu primer tractament, ja va començar a principis de la dècada dels anys noranta (Observatorio Español de la Droga y las Toxicomanías, 2011). Amb relació a aquest darrer fet, però, diferents autors assenyalen que la notable disminució del consum de drogues per via parenteral produïda al llarg dels darrers decennis a l'Estat espanyol ha d'atribuir-se més a canvis de mercat o culturals que no pas a polítiques públiques específiques (Barrio et al., 2012; de la Fuente, Bravo, Barrio, Parras et al., 2003; de la Fuente et al., 2006). Dades recents situen el nombre de consumidors problemàtics d'opioides a Europa en 1,3 milions de persones (EMCDDA, 2015*a*). De fet, a escala europea els opioides —sobretot l'heroïna— són la substància principal que motiva la demanda de tractament en el 41 % dels casos (EMCDDA, 2015*a*). Així mateix, en el 81 % dels casos de sobredosi fatal a Europa es troba aquesta substància psicoactiva (EMCDDA, 2015*a*), i s'estima que la mortalitat anual per qualsevol causa se situa, en el cas dels consumidors d'opioides, entre 10.000 i 20.000 persones (EMCDDA, 2014). El darrer informe publicat per l'Observatorio Español de la Droga y las Toxicomanías (OEDT, 2016) assenyala que els opioides són la substància principal que motiva l'admissió a tractament en el 16 % o en el 25 % dels episodis de tractament si es considera o no, respectivament, l'alcohol (el tabac no es considera en cap de les dues estimacions). El mateix informe situa el nombre de PUDVP i de consumidors problemàtics d'heroïna a l'Estat espanyol l'any 2013 en 9.879 i 65.648 persones, respectivament (OEDT, 2016).

Tant els informes esmentats de l'EMCDDA (2014, 2015*a*) com estudis recents (Des Jarlais, Kerr, Carrieri, Feelemyer i Arasteh, 2016; Hedrich et al., 2013; Rácz, Gyarmathy i Csák, 2016; Sarafis i Tsounis, 2014) mostren que la disminució sostinguda del nombre de nous casos de VIH en PUDVP sembla que s'ha interromput, si més no momentàniament, arran del repunt de la taxa d'incidència en alguns països concrets com ara Grècia i Romania, molt probablement a causa d'una menor cobertura dels programes preventius derivada de la recessió econòmica (Hedrich et al., 2013; Sarafis i Tsounis, 2014). Pel que fa a l'Estat espanyol, ara per ara no es disposa de dades que suggereixin aquest canvi de tendència produït en territoris sotmesos igualment a importants retallades en la despesa pública destinada a l'àmbit de la salut i la sanitat. No obstant això, sí que diferents autors (per exemple, Vallejo et al., 2015) han fet al·lusió al fet que l'actual nivell de cobertura de les intervencions de reducció de danys podria no estar en consonància amb les necessitats reals. En qualsevol cas, cal destacar diferents resultats de dos estudis especialment rellevants realitzats a l'Estat espanyol durant els darrers deu anys. El primer és l'estudi ITINERE (de la Fuente et al., 2005), basat en el seguiment d'una cohort inicial de 991 joves (menors de 30 anys) consumidors d'heroïna reclutats en la comunitat (independentment dels centres de tractament de drogodependències) a les ciutats de Barcelona, Madrid i Sevilla, mitjançant tècniques de mostreig no probabilístic (essencialment, un sistema de bola de neu amb incentius per participar i captar o nominar altres participants). El reclutament es va fer entre els mesos d'abril del 2001 i desembre del 2003, i les entrevistes de seguiment anual van finalitzar el mes de juliol del 2006. El segon dels estudis està vinculat amb els diferents subestudis transversals fets des de l'any 1993 pel Centre d'Estudis Epidemiològics sobre les Infeccions de Transmissió Sexual i Sida de Catalunya (CEEISCAT, 2011) i vinculats amb el monitoratge de la prevalença tant de les infeccions esmentades com de les conductes associades a la seva transmissió en les PUDVP. Aquests subestudis transversals duts a terme pel CEEISCAT se centraven en mostres de PUDVP reclutades al carrer i a les zones de venda i consum de drogues. A partir, però, del subestudi fet entre els mesos d'octubre del 2008 i març del 2009 (CEEISCAT, 2011), la metodologia va variar, amb l'objectiu d'intentar obtenir una mostra més representativa de la població usuària de drogues injectables de Catalunya, incloent-hi una submostra de PUDVP procedent d'altres països. Així, les PUDVP es van reclutar arreu del territori català en centres de reducció de danys mitjançant un mostreig de conveniència, i es va estratificar per tipus de centre i per país d'origen dins de cada centre (CEEISCAT, 2011).

Pel que fa al primer dels dos estudis esmentats, cal destacar que l'estudi ITINERE mostra: *a*) una prevalença elevada de la infecció pel VIH (25,8 %) en joves consumidors d’heroïna (Barrio et al., 2007); *b*) una força d’infecció per al VIH en PUDVP (0,06 per persona i any) superior a la de la majoria de països de la Unió Europea (Sutton et al., 2008); *c*) unes taxes extremadament elevades de prevalença (73,3 %) i d’incidència (39,8 per 100 persones i any) de la infecció pel virus de l’hepatitis C (VHC) en joves consumidors d’heroïna —en cas d’excloure d’aquesta darrera estimació els consumidors que no s’havien injectat durant el període de seguiment, la taxa de seroconversió se situa en 52,9 per 100 persones i any— (Vallejo et al., 2015); i *d*) una taxa ajustada de letalitat per sobredosi d’opioides del 4,2 % (és a dir, de cada 100 episodis de sobredosi 4 resultaven mortals) en joves consumidors d’heroïna (Espelt, Barrio et al., 2015). Per la seva banda, els resultats del darrer subestudi transversal realitzat pel CEEISCAT mostren: *a*) que la prevalença de la infecció pel VIH en PUDVP reclutades en centres de reducció de danys de Catalunya entre els mesos de novembre del 2012 i maig del 2013 es manté elevada, i se situa en un 30,6 % (CEEISCAT, 2015); *b*) que, en el cas dels nous injectors de drogues (PUDVP des de fa cinc anys o menys), la prevalença esmentada se situa en el 16,7 % (14,9 % i 27 % per a ciutadans originaris de l’Estat espanyol o immigrants, respectivament) (CEEISCAT, 2015); *c*) que el consum injectat d’heroïna com a substància principal augmenta significativament entre els immigrants (del 40,3 % en el període 2008-2009 al 51 % en el període 2012-2013); i *d*) que, si bé la prevalença d’acceptar o passar xeringues usades mostra una tendència decreixent entre 2008-2009 i 2012-2013 tant en el grup d’injectors espanyols com en el d’immigrants, la de les pràctiques indirectes de compartir material d’injecció es manté estable —cal recordar, però, que en el període 2008-2009 se situava en el 55,2 % (Folch et al., 2012)— i, entre el col·lectiu d’immigrants, la conducta de compartir un altre material d’injecció (com ara la cullera, el filtre o l’aigua per preparar la dosi) mostra una tendència creixent significativa, i passa del 52,6 % el 2008-2009 al 67,6 % el 2012-2013 (CEEISCAT, 2015).

1.2. Els programes de reducció de danys en el context del VIH i el consum injectat de drogues

Les persones usuàries de drogues no són un grup homogeni pel que fa a la disposició o preparació per abandonar-ne el consum. No obstant això, fins fa poques dècades, l’oferta única d’intervencions orientades i dissenyades, quasi exclusivament, per a usuaris clarament motivats per abandonar el consum de substàncies psicoactives, ha caracteritzat la història de l'abordatge de les conductes addictives fins a la progressiva implementació de les intervencions de reducció de danys i la conseqüent cohabitació d'ambdós enfocaments en una complementarietat no sempre harmònica, basada en una actitud pragmàtica derivada de l'evidència del fet que els objectius preventius o terapèutics i les intervencions que no estan orientats a les necessitats ni a la disposició motivacional de l'usuari de drogues són difícilment assolibles i escassament efectives, respectivament (Trujols, Salazar i Salazar, 1999).

Abans, però, de prosseguir, és de justícia reconèixer, en paraules d'una activista política i usuària de drogues per via parenteral, un fet massa sovint oblidat i una possible diferenciació que el fet mateix comportaria segons l'autora: «Harm reduction, as a potential method of reducing drug-related harms, has long been practised informally by illicit drug users the world over since people starting using drugs for the myriad of reasons that we do [...]. The (formal) approach to reducing harmful illicit drug use, which I have come to call "professional harm reduction", or PHR, is a recent newcomer to the discourse on drugs/drug users. I use the term "professional" to connote the institutionalized and, more importantly, the "professionalized" character that HR has come to take on» (White, 2001, p. 451).

Tres factors han tingut un paper fonamental a l'hora d'impulsar i afavorir la necessitat i el desenvolupament dels programes (professionals) de reducció de danys (Trujols, Salazar et al., 1999):

- ✓ L'evidència contrastada tant de la limitada efectivitat com de l'insuficient atractiu de l'oferta terapèutica clàssica centrada únicament en programes d'intervenció orientats a l'abstinència.

- ✓ L'aparició del VIH i la ràpida expansió de la infecció pel VIH entre les PUDVP.

- ✓ La progressiva, tot i que encara força tímida en massa escenaris, tendència a modificar la relació jerarquitzada professional-usuari basada en el model mèdic tradicional de malaltia i en una percepció esbiaixada i excloent de la persona drogodependent com a persona no competent.

És imprescindible destacar la rellevància de cadascun d'aquests tres factors en la configuració d'un marc favorable per a les polítiques i les intervencions de reducció de danys, i no atribuir el seu desenvolupament únicament a l'aparició de la síndrome d'immunodeficiència adquirida (SIDA). Diversos autors assenyalen exemples concrets de polítiques i intervencions anteriors a l'aparició del VIH —alguns es remunten fins i tot al segle XIX (Nadelmann, McNeely i Drucker, 1997)—, clarament subsumibles en els plantejaments de la reducció de danys, fet que demostra que no es tracta d'una perspectiva o abordatge nou, sinó que té un origen anterior a l'aparició de l'epidèmia de la SIDA. No obstant això, aquesta epidèmia ha dotat la perspectiva de la reducció de danys amb un impuls més gran, ha propiciat la consolidació de la qüestió «drogues» en l'agenda de la salut pública i ha estat el motiu principal pel qual tant responsables polítics i gestors com professionals de l'atenció a la salut, inicialment reticents, han possibilitat la implementació d'aquest tipus de programes.

Els programes de reducció de danys (PRD) poden definir-se, globalment i succintament, com el conjunt de les accions individuals i col·lectives dirigides a minimitzar els efectes físics, psíquics i socials negatius associats al consum de drogues (Mino, 2000). Es tracta, doncs, d'una aproximació o enfocament eminentment humanitari i pragmàtic dirigit a la millora de la qualitat de vida dels usuaris de drogues (Collins et al., 2012). Així mateix, cal remarcar que el terme *reducció de danys* travessa tots els aspectes del consum de substàncies psicoactives i que els PRD no es dirigeixen exclusivament a PUDVP (no obstant això, aquestes persones constitueixen el col·lectiu d'usuaris de substàncies psicoactives en el qual es troba un desenvolupament, una diversificació i un estudi de l'efectivitat dels PRD més importants). Com afirma Newcombe (1992), els danys associats al consum de substàncies psicoactives han de ser considerats des d'una perspectiva multidimensional. Amb relació al nivell del dany, el receptor o destinatari pot ser la persona usuària de drogues, la seva xarxa sociocomunitària més propera (família, amics i veïnat) o la societat en general i, pel que fa al tipus de dany, a més dels relatius a la salut, també entren en joc els danys socials i econòmics. Així mateix, la morbimortalitat associada al consum de drogues per via parenteral —la prevenció, reducció o minimització de la qual és un dels principals objectius de les intervencions i PRD dirigits a PUDVP— no està relacionada únicament amb el VIH/SIDA. L'hepatitis C, els intents de suïcidi, els accidents, les reaccions adverses o els episodis de sobredosi —accidentals o no— són alguns exemples d'altres factors que contribueixen a l'excés de morbimortalitat experimentat per les PUDVP (Darke, Degenhardt i Mattick, 2007; Degenhardt et al., 2011; Martin, Sampson, Cerdá i Galea, 2015; Mathers i Degenhardt, 2014; Mathers et al., 2013; Wiessing et al., 2014). Finalment, cal emfatitzar que aquests danys estan determinats en gran mesura per múltiples factors individuals, relacionals, sociomaterials i macroeconòmics, entre d'altres (Cooper et al., 2016; Des Jarlais et al., 2012; Ezard, 2001; Friedman, Rossi i Braine, 2009; Friedman et al., 2016; Nikolopoulos et al., 2015; Rhodes, 2002, 2009; Rhodes, Singer, Bourgois, Friedman i Strathdee, 2005; Rhodes et al., 2012; Strathdee, Beletsky i Kerr, 2015; Strathdee et al., 2010), motiu pel qual aquestes variables mediadores —essencialment, però, i de forma pràcticament exclusiva, les diferents operativitzacions de la variable risc (per exemple, compartir xeringues o un altre material per a la injecció, pràctiques sexuals de risc)— han estat considerades variables subrogades o *proxy* de l'efectivitat dels PRD, i les intervencions que minimitzen les variables mediadores esmentades —sense eliminar necessàriament el consum de drogues— han estat igualment englobades en la reducció de danys (Blankenship, Friedman, Dworkin i Mantell, 2006; Degenhardt et al., 2010; Gupta, Parkhurst, Ogden, Aggleton i Mahal, 2008; Sumartojo, 2000). Per aquest motiu, s'opta sovint per l'expressió *intervencions o programes de reducció de riscos i danys*. Tanmateix, a vegades sí que es distingeix entre reducció de riscos i reducció de danys, i es reserva el terme *reducció de riscos* per a les intervencions no vinculades amb contextos i col·lectius marginalitzats. Així, la diferència no radicaria en la mirada ni en la filosofia de treball, sinó en els entorns i col·lectius amb els quals es treballa (Martínez-Oró i Pallarés-Gómez, 2013*b*). De fet, a Catalunya, els documents rectors del Departament de Salut mateix reflecteixen i reforcen aquesta distinció (Parés i Bouzo, 2015).

D'una manera coherent amb la naturalesa multidimensional del dany esmentada anteriorment i tal com es pot constatar a continuació en una breu presentació dels principals PRD dirigits a usuaris d'heroïna (per a una revisió més exhaustiva d'aquests i altres PRD i riscos, vegeu Erickson, Riley, Cheung i O'Hare, 1997; Heather, Wodak, Nadelmann i O'Hare, 1993; Laespada i Iraurgi, 2009; Marlatt, Larimer i Witkiewitz, 2012; Martínez-Oró i Pallarés-Gómez, 2013*a*; O'Hare, Newcombe, Matthews, Buning i Drucker, 1992; Rhodes i Hedrich, 2010a; Ritter i Cameron, 2005; Trujols, Salazar et al., 1999), la reducció de danys ha de ser igualment multidimensional (Brettle, 1991) i organitzar i englobar la pràctica simultània de diferents serveis o programes socials i sanitaris —accessibles, de qualitat i amb una cobertura adequada—, ja que qualsevol d’aquests programes és, per si sol, insuficient. En paraules de Rhodes i Hedrich (2010*b*, p. 19), la reducció de danys ha de concebre’s com una «combination intervention».

1.2.1. Programes de distribució i/o intercanvi de xeringues

L’any 1981, la Rotterdamse Junkiebond —una associació de PUDVP activistes de Rotterdam— va iniciar el primer programa de distribució de xeringues, amb l’objectiu de disminuir la transmissió del virus de l’hepatitis B (Grund et al., 1992*a*, 1992*b*; Nadelmann et al., 1997). No obstant això, existeix alguna experiència anterior puntual i de menor abast (Chapple, 1967). La iniciativa dels usuaris holandesos va ser posteriorment assumida pel servei municipal de salut per prevenir l’expansió de l’epidèmia de la SIDA. Als Estats Units, tot i l’existència d’alguna iniciativa individual de distribució pública de material estèril d’injecció a partir de finals de l’any 1986 (Lurie et al., 1993), el primer programa d’intercanvi de xeringues va iniciar-lo l’any 1988 un exusuari d’heroïna a la localitat de Tacoma (Marlatt, 1998). A l’Estat espanyol, el primer programa de distribució i intercanvi de xeringues es va desenvolupar l’any 1988 a Bilbao i rodalies: fou la iniciativa de la Comisión Ciudadana Anti-Sida de Vizcaya (Arroyuelo i Fernández de Garayalde, 1991; Menoyo, Zubía, Urzelai i Zulaika, 1994). L’objectiu principal d’aquests programes és la minimització de la pràctica de compartir el material d’injecció, limitant així la possibilitat de contagi de malalties de transmissió sanguínia a altres PUDVP. Nombrosos estudis han demostrat que els programes d’intercanvi de xeringues disminueixen la pràctica de compartir material d’injecció i, conseqüentment, redueixen la incidència del VIH en la població de PUDVP; paral·lelament, no s’evidencia un augment del nombre d’aquestes persones ni dels nivells de consum en l’àmbit comunitari. La integració d’aquests estudis en les síntesis metaanalítiques realitzades per Ksobiech (2003, 2006) mostren de forma concloent que els programes d’intercanvi de xeringues:

- ✓ no incrementen de manera estadísticament significativa la freqüència de la conducta d’injectar-se, i per tant mostren que un dels principals temors dels crítics dels programes esmentats eren infundats;

- ✓ disminueixen de manera estadísticament significativa les pràctiques directes de compartir material d'injecció (rebre o donar una xeringa usada); i
- ✓ disminueixen de manera estadísticament significativa les pràctiques indirectes de compartir material d'injecció (donar o rebre la droga dissolta en una altra xeringa —*front/backloading*— o compartir altres estris o material com ara la cullera, el filtre o l'aigua per preparar la dosi).

Dues revisions sistemàtiques fetes recentment (Abdul-Quader et al., 2013; Aspinall et al., 2014) —amb síntesi narrativa i metaanalítica dels estudis, respectivament— han confirmat igualment l'efectivitat dels programes d'intercanvi de xeringues en la reducció de la transmissió del VIH en PUDVP. Els autors mateixos de la metaanàlisi (Aspinall et al., 2014), però, reconeixen que probablement altres PRD han contribuït també a l'esmentada reducció del risc de transmissió del VIH, fet que emfatitza, doncs, la necessària complementarietat dels diferents PRD.

1.2.2. Sales per a una injecció més segura o dispositius assistencials de venopunció

Un nombre creixent d'estudis suggereix que les sales per a una injecció més segura o dispositius assistencials de venopunció poden complementar altres intervencions més clàssiques en la prevenció del VIH en PUDVP. La revisió sistemàtica de Kerr, Kimber, Debeck i Wood (2007) mostra que les sales per a una injecció més segura, pel fet de proporcionar un espai higiènic i amb supervisió d'un professional sanitari per al consum de drogues, atrau un subgrup de PUDVP que presenten una sèrie de variables associades a una vulnerabilitat més gran d'infecció pel VIH (per exemple, persones que s'injecten de manera regular i no esporàdica, injectors sense llar). Així mateix, les sales per a una injecció més segura, comparativament amb altres PRD i riscos, proporcionen un període temporal més llarg de contacte en el qual es pot facilitar formació per a un consum més segur. Finalment, els estudis revisats per Kerr et al. (2007) mostren també que aquests dispositius assistencials propicien una disminució de les pràctiques directes i indirectes de compartir material d'injecció en les PUDVP que acudeixen a aquests dispositius.

Una posterior revisió sistemàtica publicada recentment (Potier, Laprévote, Dubois-Arber, Cottencin i Rolland, 2014) confirma que les sales per a una injecció més segura són eficaces a l’hora d’atreure les PUDVP més marginalitzades, de promoure condicions més segures per a la injecció, de facilitar l’accés als serveis d’atenció primària i de reduir la freqüència de sobredosis. Així mateix, la presència d’aquests dispositius no s’associa a un augment d’esdeveniments negatius en els entorns circumdants (per exemple, tràfic de drogues o altres actes delictius), però sí a una reducció tant en el nivell d’injecció en espais públics com en el de xeringues abandonades en aquests llocs (Potier et al., 2014).

Cal destacar igualment que, donada la capacitat d’atracció d’aquests dispositius en el cas de les PUDVP que no es troben en contacte amb altres programes o centres d’atenció, les sales per a una injecció més segura presenten un important potencial per a la realització de les proves de detecció d’anticossos anti-VIH, especialment gràcies a la utilització creixent de les proves ràpides de detecció d’anticossos davant el VIH. Així mateix, la incorporació dels tractaments amb agonistes opioides a les sales per a una injecció més segura podria augmentar igualment la utilitat preventiva d’aquest tipus de dispositius.

1.2.3. Programes de distribució de naloxona

La naloxona és un antagonista opioide pur. Tot i que presenta una afinitat més gran pels receptors mu, es tracta d’un antagonista competitiu de tots els receptors d’opioides (Torrens, Fonseca, Galindo i Farré, 2015). S’utilitza habitualment per via parenteral —l’eficàcia de l’administració intranasal sembla, però, similar (Sabzghabaee, Eizadi-Mood, Yaraghi i Zandifar, 2014)—, en els serveis d’urgències per revertir les sobredosis d’heroïna (Torrens et al., 2015).

La distribució de naloxona als usuaris d’heroïna —emmarcada en un programa de prevenció i actuació en cas de sobredosi d’heroïna (Arribas-Ibar, Sánchez-Niubò, Majó, Domingo-Salvany i Brugal, 2014; Espelt, Majó et al., 2015; Sarasa-Renedo et al., 2014)— perquè ells mateixos puguin actuar davant d’una sobredosi patida per un altre usuari, seria doncs una potencial estratègia de reducció de la morbimortalitat associada als episodis de sobredosi d’heroïna o altres agonistes opioides. Els continguts d’aquests programes de prevenció i actuació en cas de sobredosi se centren essencialment en: *a*) els factors de risc de patir una sobredosi; *b*) la identificació d'una sobredosi; i *c*) les accions que cal fer en cas de presenciar una sobredosi (per exemple, trucar al telèfon únic d'emergències, injectar la naloxona intramuscular a l'espatlla, col·locar la persona afectada en posició lateral de seguretat, fer les maniobres de reanimació cardiopulmonar). En funció dels continguts exposats i del format i la metodologia dels tallers o sessions, la seva durada oscil·la entre deu minuts i una hora segons la revisió sistemàtica de Clark, Wilder i Winstanley (2014). Aquesta revisió sistemàtica conclou que la participació en aquests programes està associada a reversions d'episodis de sobredosi, a un nivell més alt de coneixements i habilitats per respondre adequadament davant un episodi de sobredosi i a una capacitació per administrar de manera segura la naloxona (Clark et al., 2014).

Aquests resultats són confirmats per tres revisions sistemàtiques posteriors (EMCDDA, 2015*b*; McDonald i Strang, 2016; Mueller, Walley, Calcaterra, Glanz i Binswanger, 2015). Igualment destacables són els resultats de dues metaanàlisis recents. La primera conclou que, per cada 100 usuaris formats en programes de distribució de naloxona, el 9,2 % dels *kits* distribuïts seran utilitzats per a administració entre iguals durant els primers tres mesos posteriors a la seva distribució (McAuley, Aucott i Matheson, 2015). La segona metaanàlisi mostra que l'administració de naloxona per part d'un altre usuari, comparada amb la no-administració, s'associa a un augment estadísticament significatiu de la probabilitat de recuperació (Giglio, Li i DiMagio, 2015).

1.3. Els tractaments de manteniment amb metadona

La metadona és un agonista opioide semisintètic (Torrens et al., 2015), utilitzat com a tractament de manteniment per a la dependència d'heroïna arran dels excel·lents resultats obtinguts pels estudis iniciats l'any 1963 per Dole i Nyswander al Rockefeller University Hospital (Dole i Nyswander, 1980; Lowinson, 1981; Lowinson, Marion, Joseph i Dole, 1992). La metadona és un agonista dels receptors d'opioides —els receptors mu principalment, però també els delta i, en menor mesura, els kappa—, que presenta igualment propietats antagonistes dels receptors de *N*-metil-D-aspartat (NMDA) (Torrens et al., 2015). La metadona utilitzada en els tractaments de manteniment és una barreja racèmica 50:50 de dos enantiòmers anomenats (*R*)- o levo- o L-metadona i (*S*)- o dextro- o D-metadona. Per bé que es considera que la (*R*)-metadona seria la responsable de la majoria, si no la totalitat, dels efectes terapèutics del tractament de manteniment amb metadona (TMM), aquests tractaments utilitzen habitualment la (*R*,*S*)-metadona a causa del seu inferior cost de producció i arran de les evidències d'uns efectes terapèutics similars als de la (*R*)-metadona sola (Torrens et al., 2015). Des d'un punt de vista farmacològic, l'objectiu dels TMM —i dels altres tractaments de manteniment amb agonistes opioides (TMAO)— és estabilitzar la neuroquímica del cervell substituint opioides de curta durada d'acció, com l'heroïna, per opioides de llarga durada (Torrens et al., 2015).

El desenvolupament dels TMM ha representat un substancial avenç en l'abordatge de la dependència d'heroïna (Strain i Stitzer, 1999; Tober i Strang, 2003; Wall i Haga, 2003; Ward, Mattick i Hall, 1998) i, actualment, és el tractament més utilitzat en aquests casos (Torrens et al., 2015). A més de la metadona, però, s'utilitzen altres agonistes opioides en tractaments de manteniment dirigits igualment a persones dependents d'heroïna o altres opioides. Per citar-ne únicament dos, cal destacar en primer lloc la buprenorfina —utilitzada darrerament, per evitar-ne el consum per via endovenosa, en combinació amb la naloxona—, un agonista opioide parcial, per l'increment creixent del seu ús en TMAO (EMCDDA, 2014, 2015*a*). Per a una revisió de l'eficàcia dels tractaments de manteniment amb buprenorfina i buprenorfina/naloxona, vegeu Fareed, Vayalapalli, Casarella i Drexler (2012) i Mattick, Breen, Kimber i Davoli (2014). En segon lloc, cal remarcar també la diacetilmorfina o heroïna, que actua com un agonista mu a través dels seus metabòlits 6-monoacetilmorfina (6-MAM) i morfina (Torrens et al., 2015), per la seva utilització —per bé que d'una manera incipient i en molt pocs països— en pacients amb mala resposta als TMM i als tractaments de manteniment amb buprenorfina/naloxona. Per a una revisió de l'eficàcia dels tractaments de manteniment amb heroïna, poden consultar-se els treballs de Ferri, Davoli i Perucci (2011) i Strang et al. (2015).

A causa, doncs, de la creixent utilització d'altres agonistes opioides —la buprenorfina, bàsicament— com a tractament de manteniment, algunes de les revisions sistemàtiques més recents sobre els TMM avaluen, de fet, l'efectivitat global de diferents TMAO i tendeixen a utilitzar d'una manera cada vegada més freqüent el terme *TMAO* —o el de *tractament amb substitutius opioides*— i no únicament el de *TMM*. No obstant això, la totalitat de les revisions sistemàtiques sobre els TMAO que citem o esmentem a continuació fan referència essencialment als TMM, perquè aquesta modalitat de tractament de manteniment, pel fet d'haver-se implementat àmpliament i des de fa més dècades, disposa d'un nombre substancialment superior d'estudis realitzats i publicats.

Nombroses revisions sistemàtiques acompanyades d'una síntesi metaanalítica dels resultats mostren l'efectivitat —en el cas de dues de les revisions que se citen a continuació seria més adequat parlar, però, d'eficàcia perquè se centren en assaigs clínics controlats i aleatoritzats— dels TMM amb relació a les següents variables o indicadors:

- ✓ retenció en tractament (per exemple, Farré, Mas, Torrens, Moreno i Camí, 2002; Mattick, Breen, Kimber i Davoli, 2009);
- ✓ disminució del consum d'heroïna o altres opioides no prescrits (per exemple, Farré et al., 2002; Gowing, Farrell, Bornemann, Sullivan i Ali, 2011; Marsch, 1998; Mattick et al., 2009);
- ✓ reducció de l'activitat delictiva (per exemple, Marsch, 1998; Sun et al., 2015); i
- ✓ reducció de la mortalitat (per exemple, Caplehorn, Dalton, Haldar, Petrenas i Nisbet, 1996; Degenhardt et al., 2011; Desmond i Maddux, 2000).

Així mateix, nombrosos estudis han demostrat de manera consistent que els TMM estan associats a un menor risc de contraure el VIH. La revisió sistemàtica amb síntesi metaanalítica de Gowing et al. (2011) ha mostrat que els TMAO disminueixen de manera estadísticament significativa la conducta d'injectar-se (mesurada a través de la proporció de persones que s'injecten i/o de la freqüència del consum d'heroïna per via parenteral). Així mateix, aquests tractaments disminueixen de manera estadísticament significativa també les pràctiques de compartir el material d'injecció. Aquesta reducció, tal com afirmen els autors de la revisió sistemàtica, podria ser deguda a la disminució de la conducta d'injectar-se, però no és possible assegurar-ho basant-se en les dades disponibles. Finalment, les dades relatives a les puntuacions obtingudes en escales de valoració de pràctiques de risc relacionades amb el consum parenteral d'heroïna mostren igualment una disminució estadísticament significativa associada al TMAO. En la mateixa línia d'aquests resultats, una metaanàlisi posterior (MacArthur et al., 2012) mostra que el fet d'estar en TMAO s'associa a una reducció del 54 % en el risc d'infecció pel VIH.

Atès que els pacients en TMAO seropositius al VIH presenten una disposició més gran a iniciar el tractament antiretroviral (Wood et al., 2005) i, a la vegada, una adhesió i una resposta a aquest tractament superiors a les presentades per les persones dependents d'heroïna que no estan en TMAO (Malta, Magnanini, Strathdee i Bastos, 2010; Malta, Strathdee, Magnanini i Bastos, 2008), l'impacte preventiu indirecte dels TMAO respecte a la incidència del VIH podria ser igualment rellevant (Anema, Wood i Montaner, 2008; de Vos, Prins, Coutinho, van der Helm i Kretzschmar, 2014; Wood, Milloy i Montaner, 2012). De fet, recentment, i mitjançant la tècnica estadística del model estructural marginal, s'ha demostrat un efecte causal entre el TMAO i l'adhesió al tractament antiretroviral (Nosyk et al., 2015), en un context de finançament públic i accés generalitzat a ambdós tractaments.

Per a una anàlisi històrica detallada del procés d'implantació i desenvolupament dels TMM a l'Estat espanyol, vegeu Barbero (1999), de Torres (1986) i Rodríguez-Martos (1994). En poques paraules, però, el mateix Barbero (1999, p. 208) resumeix de forma impecable aquest procés afirmant que «su presencia, prácticamente anecdótica hasta hace muy poco tiempo, y sus condiciones llevan a pensar que han estado más dirigidos a satisfacer las necesidades de la opinión pública (con sus distintas acepciones de moral pública, orden público e imagen pública), que a la resolución de los problemas asociados, potenciales y reales, de la población drogodependiente, en una perspectiva de salud pública».

La caracterització més completa de l'organització, el tractament aplicat i la població atesa a la totalitat dels diferents centres que configuren la xarxa dels TMM a l'Estat espanyol data de l'any 1994 (Domingo-Salvany et al., 1999), any en el qual una comunitat autònoma no disposava encara de cap centre de TMM. Tot i haver transcorregut més de dos decennis des de la realització de l'estudi, val la pena destacar-ne alguns resultats —i posar-los en relació amb la situació epidemiològica del VIH/SIDA a l'Estat espanyol en aquell moment i/o amb la perspectiva de la reducció de danys plenament vigent ja aleshores en altres àmbits geogràfics— per copsar millor alguns dels arguments subjacents a l'afirmació de Barbero (1999). Tant la petició del pacient dependent d'heroïna de ser inclòs en TMM com el fet de ser VIH-negatiu eren puntuats com a motius importants d’inclusió en TMM per menys d’un 25 % dels centres (Domingo-Salvany et al., 1999). Paral·lelament, i pel que fa als motius d’expulsió del centre de TMM, un 50 % dels centres consideraven una anàlisi d’orina positiva a heroïna com a important. Globalment, doncs, el compliment dels centres amb els procediments considerats efectius en la prevenció del VIH era únicament moderada (Domingo-Salvany et al., 1999).

1.3.1. Breus apunts sobre la situació global i local dels PRD en general i dels TMM en particular

Dels 158 països que reconeixen que en el seu territori es consumeixen drogues il·legalitzades per via parenteral, únicament 91 inclouen un cert suport explícit a la reducció de danys en documents sobre polítiques d’àmbit nacional (Stone, 2014). Així mateix, únicament 90 països disposen de programes d’intercanvi de xeringues i 80 de TMAO, i aquesta xifra baixa a 8 en el cas de les sales per a una injecció més segura (Stone, 2014).

Per a una correcció més gran en la interpretació d’aquestes dades cal fer dues precisions. La primera té a veure amb les habituals diferències entre el nivell discursiu i el de les pràctiques, diferenciació gens banal a l’hora d’interpretar les referències explícites de suport a la reducció de danys en alguns documents oficials sobre polítiques d’àmbit nacional. La segona, més centrada en les respostes operatives de reducció de danys, afegeix que la presència d’un determinat PRD en un territori concret no comporta cap qualificatiu implícit sobre la disponibilitat, l’accessibilitat o la cobertura d’aquell programa en l’àmbit geogràfic concret. De fet, pot tractar-se de programes no desenvolupats ni finançats per l’estat (únicament tolerats), d’experiències molt limitades pel que fa al nombre o la cobertura o, fins i tot, de programes experimentals o pilot en aquell territori concret. Un exemple manifest d’aquesta segona precisió és, per exemple, la pràcticament nul·la presència dels programes d’intercanvi de xeringues en l’àmbit penitenciari (únicament en 8 dels 90 països que en disposen en l’àmbit comunitari; Stone, 2014) o la limitada cobertura dels TMM en múltiples àmbits geogràfics encara avui en dia (C. M. Jones, Campopiano, Baldwin i McCance-Katz, 2015; Mathers et al., 2010). En estreta connexió amb aquest darrer fet, cal destacar un estudi fet recentment a Sant Petersburg, capital de la província de

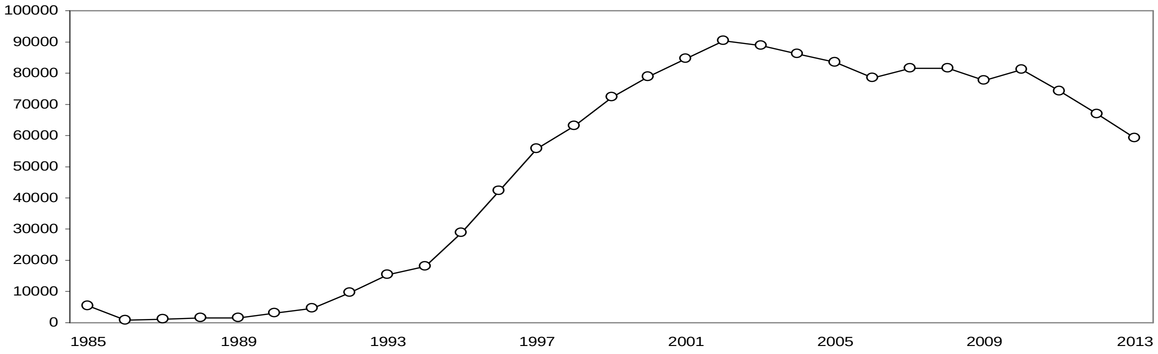
Leningrad (Heimer, Lyubimova, Barbour i Levina, 2016). Com és ben sabut, els TMM, tot i que la metadona està inclosa a la llista de medicaments essencials segons l'Organització Mundial de la Salut des de mitjan la dècada passada (World Health Organization, 2005), són il·legals arreu de tota la Federació de Rússia. En aquestes condicions de demonització de la metadona i de prohibició dels TMAO, l'estudi mostra: *a*) que el 53,3 % de les PUDVP s'injecten la metadona; i *b*) que la pràctica d'injectar-se únicament metadona, comparativament amb la d'injectar-se només heroïna o ambdues substàncies, està associada de manera estadísticament significativa a una menor freqüència tant d'injecció com d'utilització d'una xeringa usada prèviament per una altra PUDVP (Heimer et al., 2016).

En l'àmbit de la Unió Europea, s'estima que 700.000 persones estan en TMAO (EMCDDA, 2015*a*), de les quals més de dos terços (69 %) es troben en TMM i un 28 % en tractament de manteniment amb buprenorfina (modalitat principal de TMAO en sis països). Altres agonistes opioides com ara la morfina d'alliberació lenta o la diacetilmorfina (heroïna) constitueixen la substància prescrita en el 3 % restant de TMAO (EMCDDA, 2015*a*).

A l'Estat espanyol, l'any 2013 —darrer any amb dades publicades sobre aquest punt—, el nombre de persones en TMM se situa en 59.059 (Delegación del Gobierno para el Plan Nacional sobre Drogas, 2015), que representa la xifra més baixa des de finals de la dècada dels anys noranta (figura 1). El nombre total, però, de persones en TMAO és de 61.954, perquè 2.895 d'elles estan en tractament de manteniment amb buprenorfina/naloxona. Així mateix, l'any 2011, darrera data amb informació disponible sobre el nombre de punts disponibles d'intercanvi de xeringues, aquesta dada se situa en 1.506 (Delegación del Gobierno para el Plan Nacional sobre Drogas, 2013). Amb relació a les variables de disponibilitat i cobertura que s'esmentaven unes línies més amunt i pel que fa al nostre àmbit geogràfic de referència, pot afirmar-se que l'Estat espanyol disposa actualment d'una xarxa acceptable de TMAO i de programes d'intercanvi de xeringues (Bravo et al., 2007; de la Fuente et al., 2006; Torrens, Fonseca, Castillo i Domingo-Salvany, 2013; Vallejo et al., 2015). No obstant això, cal recordar, tal com han mostrat diversos autors (Barrio et al., 2012; de la Fuente, Bravo, Barrio, Parras et al., 2003; de la Fuente, Bravo, Barrio i Silva, 2003; de la Fuente et al., 2006), que les greus conseqüències —mortals per a moltes PUDVP— del retard en la implantació i el desenvolupament dels PRD a l'Estat espanyol haurien estat molt menors amb respostes oportunes i basades en evidències, deixant al marge apriorismes ideològics i interessos polítics i professionals.

De fet, a mitjan anys noranta, de la Fuente i Barrio (1996, p. 256) ja assenyalaven que «en los años 1986-1987 ya se disponía de evidencias epidemiológicas claras sobre la dimensión del problema de la infección por el VIH en los inyectores y podía preverse su dinámica expansiva y el impacto que iba a tener sobre la salud. Igualmente, en los años 1988-1989, ya era patente la tendencia rápidamente creciente de la mortalidad por reacción aguda tras el consumo de drogas. Por lo tanto, en ningún otro país de Europa hubiese estado más justificado el desarrollo urgente de los PRD».

Figura 1. Evolució del nombre de persones en tractament de manteniment amb metadona a l'Estat espanyol (1985-2013)



Font: elaboració pròpia a partir de les dades procedents de les memòries anuals de la Delegación del Gobierno para el Plan Nacional sobre Drogas.

Més concretament, Barrio et al. (2012) mostren que, pel que fa als TMM, no es va assolir un nivell mitjà de cobertura (20,8 %) fins a l'any 1996, és a dir, onze anys després del nivell més alt d'incidència de la infecció pel VIH en PUDVP (1985), cinc anys després de la taxa més elevada de morts per sobredosi d'opioides (1991) i quatre anys després del cim en el nivell de necessitat dels TMM (1992). Així mateix, un nivell alt de cobertura (42,9 %) no es va assolir fins a l'any 1999. Per a una interpretació adequada d'aquests nivells de cobertura, cal precisar que, en el cas dels TMAO, i d'acord amb les organitzacions internacionals, es defineix un nivell mitjà i alt de cobertura quan un 20-40 % i més d'un 40 %, respectivament, de persones dependents d'opioides es troben en TMAO (World Health Organization [WHO], United Nations Office on Drugs and Crime [UNODC] i Joint United Nations Programme on HIV/AIDS [UNAIDS], 2009). Tal com mostra l'estudi de Barrio et al. (2012), la situació en el cas dels programes d'intercanvi de xeringues ha estat similar o pitjor: un nivell mitjà (entre 100 i 200 xeringues distribuïdes per PUDVP i any; WHO, UNODC i UNAIDS, 2009) no es va assolir fins a l'any 2000 (105 xeringues), és a dir quinze anys després del cim en la taxa d'incidència de la infecció pel VIH en PUDVP (1985), de quinze a deu anys després dels nivells més elevats de prevalença de l'esmentada infecció en PUDVP (1985-1990) i vuit anys després del nivell de màxima necessitat de xeringues (1992). De fet, un nivell elevat de cobertura per part d'aquests programes no s'havia assolit encara l'any 2010 (Barrio et al., 2012).

En aquest mateixa línia i concretament a Barcelona, s'ha estimat que el 86 % de les morts per sobredosi i el 38 % de les morts associades a la SIDA en injectors d'heroïna entre 1992 i 1999 s'haurien evitat si aquestes persones haguessin estat en TMM (Brugal et al., 2005).

Tal com assenyalen diversos autors (Fafard, 2012; Lancaster, 2014; Murphy i Fafard, 2012; Trujols i Iraurgi, 2009*a*, 2009*b*), tot i que un nombre no menyspreable d'investigadors conceptualitzen l'elaboració de polítiques públiques vinculades a la salut com un procés lineal en el qual una avaluació sistemàtica i rigorosa de les evidències disponibles decanta la presa de decisions, el disseny d'aquestes polítiques públiques no és, evidentment, reductible a aquests termes. Es tracta d'un procés complex, eteri i, fins i tot, a vegades capritxós, en el qual, a part de les evidències obtingudes a través de la recerca, entren en joc múltiples i diverses influències (per exemple, creences, interessos, suport comunitari). Tal com afirmen Torrens et al. (2013, p. 138) en el cas del procés d'instauració dels TMAO a l'Estat espanyol, «moral concepts and prejudices that hinder legislation and interfere with the implementation of opioid agonist maintenance treatment have been more influential in the treatment of opioid dependence than the scientific evidence». En altres paraules, la no-implantació o el desenvolupament limitat dels TMM o d'altres PRD —en múltiples territoris i en diversos moments històrics— no es deu a una manca de dades sobre la seva eficàcia i efectivitat, sinó bàsicament a una falta de voluntat política basada en altres motivacions.

Amb aquesta afirmació, no pretenem negar que en determinats països amb una important manca de recursos econòmics aquesta mateixa manca de recursos sigui la principal barrera per a la implementació dels tractaments o programes esmentats (Wodak i McLeod, 2008), malgrat la seva demostrada cost-efectivitat (Wilson, Donald, Shattock, Wilson i Fraser-Hurt, 2015). De fet, en els casos dels països o territoris amb PRD que presentaven una cobertura globalment acceptable abans de la recent recessió econòmica, caldria diferenciar igualment entre aquells que han optat per reduir puntualment i parcialment el finançament i l'abast d'alguns PRD —abans que altres partides destinades també a l'atenció en els àmbits social i de la salut, o a altres conceptes que han valorat com a prioritaris— i aquells territoris que, sense fer cap referència a aquesta necessitat de reduir en despesa pública, aprofiten l'ocasió per dur a terme determinats canvis en l'orientació de les polítiques d'atenció a les drogodependències. Podria ser, per exemple, el cas dels canvis —marcadament contradictoris amb les evidències disponibles sobre l'eficàcia i l'efectivitat dels TMM— succeïts fa poc al Regne Unit (Luty, 2013). En qualsevol cas, però, la presa de decisions sobre projectes o programes de salut pública, com en el cas dels TMM i altres PRD, respon massa sovint a reaccions emocionals d'estigmatització i rebuig, en aquest cas, tant vers determinades substàncies psicoactives il·legalitzades com cap a les persones que les consumeixen o en depenen (Des Jarlais, Arasteh i Hagan, 2008). En aquest marc d'estigmatització i rebuig, la necessitat o l'efectivitat no són normalment aspectes rellevants que es considerin per a la implementació de determinades polítiques o programes. És la congruència o no entre el valor simbòlic de la política o programa i les esmentades emocions d'estigmatització i rebuig l'element crític per decidir (Des Jarlais et al., 2008).

Sigui com sigui, tal com es desprèn de moltes de les dades exposades en aquest apartat introductori i tal com afirmen explícitament diversos autors (de la Fuente et al., 2006; Trujols et al., 2010), no s'ha de cometre l'error de donar per resolt el problema de la injecció i de l'heroïna (o altres opioides). Atès que l'anàlisi de la relació entre les pràctiques de risc, la seroprevalença i la incidència del VIH en un moment determinat ha de prendre en consideració la història local de l'epidèmia (Des Jarlais, Braine, Yi i Turner, 2007), aquest error tindria un impacte sobre la salut pública molt més important a l'Estat espanyol —atesa l'evolució de l'epidèmia del VIH/SIDA en el col·lectiu de PUDVP en aquest àmbit geogràfic— que en altres països (de la Fuente et al., 2006).

1.3.2. Vers una avaluació de l'efectivitat dels TMM més centrada en el pacient: emfatitzant les mesures de resultats comunicats pels pacients

Des de la seva introducció en l'àmbit de l'abordatge de la dependència d'heroïna, els TMM han estat sotmesos a un procés d'avaluació i revisió constants que ha permès demostrar, tal com hem presentat de forma resumida en un subapartat anterior, l'elevada efectivitat d'aquesta modalitat de tractament per a la dependència d'opioides. No obstant això, l'efectivitat dels TMM ha estat avaluada, quasi de forma exclusiva —si més no majoritàriament—, mitjançant la utilització d'indicadors o criteris anomenats *durs* (Iraurgi, 2000; Iraurgi, Trujols, Jiménez-Lerma i Landabaso, 2011), com ara la retenció en tractament, la disminució del consum d'heroïna o altres opioides no prescrits, la reducció de la morbimortalitat o la disminució de la criminalitat, entre d'altres. Si bé tots aquests indicadors o criteris durs són vàlids i necessàriament avaluables —especialment en els estudis d'eficàcia—, sovint obeeixen a la justificació de polítiques assistencials, en altres casos busquen la conformitat i l'aprovació de la comunitat i, en qualsevol cas, estan basats en una concepció negativa de la salut i centrats en el trastorn (taula 1) (Iraurgi, 2000; Iraurgi et al., 2011).

Taula 1. Diferències entre els indicadors basats en criteris durs i flexibles

Criteris durs	Criteris flexibles
Eficaços	Efectius
Coneixement en tercera persona	Coneixement en primera persona
Necessàriament avaluables	Convenientment avaluables
Basats en una definició negativa de salut	Basats en una definició positiva de salut
Centrats en el trastorn	Centrats en el pacient
Poden obeir a la justificació de polítiques assistencials	Obeeixen a la necessitat de conèixer la perspectiva del pacient

Font: adaptat d'Iraurgi, Trujols, Jiménez-Lerma i Landabaso (2011).

Tal com assenyalen diversos autors, en múltiples àmbits de l'atenció a la salut i, si més no, al llarg dels darrers 40 anys (per exemple, Doll, 1974; Staniszewska et al., 2010, 2014), l'avaluació d'un tractament determinat ha de basar-se en els tres components següents que configuraran l'evidència (o no) de la seva efectivitat: l'evidència clínica, l'evidència econòmica i l'evidència basada en el pacient. En aquesta línia, l'avaluació dels TMM hauria de centrar-se també en l'apreciació, per part de l'usuari, tant del procés de tractament com de la resposta o canvi produït. Així doncs, l'avaluació dels resultats en la pràctica assistencial hauria d'incloure indicadors basats en l'experiència i les vivències del pacient en TMM.

Tot i que l'elecció i la consegüent avaluació de les variables de resultat per valorar l'efecte de les intervencions —i, més concretament, dels TMM— en l'àmbit dels trastorns addictius continua sent un autèntic repte tant en el cas dels assaigs clínics com, molt especialment, en el de la recerca o avaluació de resultats en la pràctica clínica habitual (Carroll et al., 2014; Donovan et al., 2012; DuPont, Compton i McLellan, 2015; Institute for Behavior and Health, 2014; Tiffany, Friedman, Greenfield, Hasin i Jackson, 2012; Vogel et al., 2016), la perspectiva dels pacients o usuaris no hi ha tingut pràcticament i dissortadament un paper gaire rellevant. Les avaluacions d'eficàcia i efectivitat dels TMM se centren en variables de resultat definides per la comunitat científica i clínica, i podrien no reflectir suficientment la perspectiva del pacient en TMM o la manera com els resultats que són importants per a ell han de ser avaluats.

De fet, múltiples autors (per exemple, Ball, Graff i Sheehan, 1974; Brown et al., 1972; Hunt i Rosenbaum, 1998; Jauffret-Roustide, 2004; Vanderplasschen et al., 2015) han assenyalat al llarg dels darrers 40 anys que la perspectiva dels usuaris no ha estat considerada una contribució especialment rellevant per a l'avaluació dels TMM, i que el conjunt de la literatura sobre aquesta qüestió és força reduït. Aquesta escassetat de treballs resulta especialment sorprenent si considerem que es tracta d'una de les modalitats de tractament més estudiades en l'àmbit de les addiccions (Hunt i Barker, 1999) i, especialment, que un dels trets característics i definitoris dels principis de la reducció de danys —i de les intervencions que s'hi basen— és la incorporació de la veu dels veritables protagonistes —els usuaris reconeguts com a interlocutors vàlids— en la definició, la implementació i l'avaluació de les intervencions, per tal que puguin respondre a les necessitats dels usuaris (Trujols, Salazar et al., 1999).

Tanmateix, amb aquesta caracterització de l'estat de la recerca sobre la perspectiva del pacient en TMM no pretenem ometre'n ni la dificultat —comparativament amb l'estudi o avaluació d'altres variables— ni l'existència de dues sublínies concretes de recerca que podrien qualificar-se de més desenvolupades o productives.

Pel que fa a la dificultat del procés de copsar o aprehendre la perspectiva del pacient en TMM, és suficientment clarificadora la lectura de la frase següent per fer-se una idea de com es considerava, pràcticament 20 anys després dels inicis dels TMM, la mera possibilitat d'intentar-ho: «What cannot be measured and is too often discounted is the individual experience of a patient stabilized on methadone, relieved of narcotic hunger, and once more able to enjoy normal living» (Lowinson, 1981). Durant la dècada dels anys noranta, amb l'auge de la recerca o avaluació de resultats en salut (Badia i Bigorra, 2000) i una utilització més freqüent dels instruments o mesures de resultats comunicats pels pacients (MRCP; Herdman i Fernández, 2013) (o PROM, segons l'acrònim anglès corresponent a *patient-reported outcome measures*), sembla que augmenten les possibilitats d'un cert canvi en aquest àmbit. Val la pena recordar que les MRCP són qüestionaris autoinformats dissenyats per avaluar qualsevol aspecte (per exemple, símptomes, estat funcional, qualitat de vida relacionada amb la salut, benestar general, satisfacció amb el tractament) vinculat amb la repercussió tant de la malaltia o trastorn com del tractament sobre la salut i funcionalitat del pacient, des de la seva pròpia perspectiva i sense la interpretació del clínic (Herdman i Fernández, 2013). De fet, actualment, l'ús de MRCP està tan estès que s'està intentant: *a*) estandarditzar com s'han de reportar aquestes mesures/dades en els assaigs clínics controlats i aleatoritzats que les utilitzen com a variable principal o secundària (Brundage et al., 2013; Calvert et al., 2013); i *b*) consensuar guies per a la revisió sistemàtica i la metaanàlisi d'aquests tipus d'estudis (Johnston, Patrick, Busse et al., 2013; Johnston, Patrick, Thorlund et al., 2013).

Pel que respecta a les sublínies de recerca que tenen un cert recorregut o desenvolupament a l'hora d'explorar la perspectiva del pacient en l'avaluació de l'efectivitat dels TMM, són destacables la relativa a la qualitat de vida relacionada amb la salut (QVRS) i la vinculada amb la satisfacció amb el tractament. Un element afavoridor, en ambdós casos, d'aquest desenvolupament més gran és la disponibilitat d'un cert nombre de MRCP genèriques —o específiques de l'àmbit de la salut mental i d'aplicació immediata al cas del TMM— per a l'avaluació d'aquestes variables en múltiples àmbits de l'atenció a la salut. Amb relació a la QVRS dels pacients en TMM, cal remarcar l'existència de dues revisions sistemàtiques (De Maeyer, Vanderplasschen i Broekaert, 2010; Feelemyer, Des Jarlais, Arasteh, Phillips i Hagan, 2014) i, en el cas del nostre àmbit geogràfic de referència, les línies de recerca vinculades amb aquesta temàtica i iniciades al llarg dels anys noranta a Barcelona i al País Basc pels grups de Marta Torrens (per exemple, Torrens, Domingo-Salvany, Alonso, Castillo i San, 1999; Torrens et al., 1997) i Ioseba Iraurgi (Iraurgi, 2000; Iraurgi, Casas, Celorio i Díaz-Sanz, 1999), respectivament.

Quant a la satisfacció amb el TMM, cal destacar un cert nombre d'estudis (per exemple, De Wilde i Hendriks, 2005; Marchand et al., 2011; Villafranca, McKellar, Trafton i Humphreys, 2006; Ward, 2000) realitzats arreu del món amb el *Client Satisfaction Questionnaire* (CSQ-8; Attkisson i Greenfield, 2004; Larsen, Attkisson, Hargreaves i Nguyen, 1979), un instrument breu i unidimensional, desenvolupat a finals dels anys setanta en l'àmbit de l'atenció a la salut mental però d'aplicació immediata al cas dels TMM en base a la redacció (força genèrica) dels seus ítems. Així mateix, i pel que fa a l'Estat espanyol, cal remarcar el desenvolupament del primer instrument específic per a l'avaluació multidimensional de la satisfacció amb el TMM (Pérez de los Cobos et al., 2002) i la realització del primer estudi d'abast nacional sobre el nivell de satisfacció amb aquesta modalitat de tractament (Pérez de los Cobos et al., 2004).

2.

Objectius i hipòtesis

Els treballs que componen aquesta tesi tenen com a denominador comú o s'emmarquen dins d'un objectiu global de generar coneixement al voltant de —i amb— la perspectiva de la persona en TMM. Amb aquest objectiu general com a eix motor i horitzó del procés de recerca, s'han portat a terme diversos estudis/treballs —uns de caràcter empíric, altres no; més concretament, i d'acord amb la tipologia d'articles aplicable seguint la normativa APA, tres estudis empírics i tres articles teòrics (American Psychological Association, 2010)—, els objectius específics dels quals s'exposen a continuació.

2.1. Objectius principals

a) Estimar la concordança entre l'avaluació realitzada pel clínic (psiquiatra i infermera) i la realitzada pel pacient mateix, de la millora del pacient en TMM. **Treball 1.**

b) Examinar la fiabilitat i la validesa de les puntuacions de la versió espanyola del *Treatment Satisfaction Questionnaire for Medication* (TSQM versió 1.4; Atkinson et al., 2004) en una mostra de pacients en TMM. **Treball 2.**

c) Identificar factors que contribueixin de forma independent i significativa a explicar la satisfacció amb el TMM. **Treball 3.**

d) Proposar un sistema classificatori dels instruments de mesura de resultats comunicats pels pacients, en funció del nivell de participació del pacient mateix en el procés de disseny i desenvolupament de l'instrument. **Treball 4.**

e) Analitzar críticament la literatura sobre les enquestes de satisfacció dels pacients amb els TMM. **Treball 5.**

f) Fer una crida —i proposar una possible alternativa— per a una avaluació de programes/resultats més centrada en el pacient o usuari. **Treball 6.**

2.2. Objectius secundaris

a) Analitzar la relació entre la millora percebuda pel pacient en TMM i la seva satisfacció amb el tractament. **Treball 1.**

b) Analitzar la relació entre la millora percebuda pel pacient en TMM i la seva opinió sobre la metadona com a fàrmac per tractar la dependència de l'heroïna. **Treball 1.**

2.3. Hipòtesis

En el cas dels tres primers treballs, les hipòtesis a contrastar són les següents:

a) L'avaluació realitzada pel clínic (psiquiatra i infermera) de la millora del pacient en TMM presenta una dèbil concordança amb la realitzada pel pacient mateix. **Treball 1.**

b) Pel que fa a les relacions amb altres variables potencialment associades o evidències de validesa convergent, les puntuacions en l'escala TSQM correlacionen: *b*.1) positivament amb una mesura d'ítem únic de la satisfacció amb la metadona com a fàrmac per tractar la dependència de l'heroïna; *b*.2) positivament amb la satisfacció amb el TMM, mesurada amb la VSSS-MT (Pérez de los Cobos et al., 2002); i *b*.3) positivament també amb dos ítems que avaluen el nivell —percebut pel pacient— de participació en el procés de presa de decisions sobre la dosi de metadona. **Treball 2.**

c) La simptomatologia psicopatològica és un factor explicatiu independent de la satisfacció amb el TMM (nivells més elevats de simptomatologia psicopatològica s'associen a una menor satisfacció amb el tractament). **Treball 3.**

3.

Mètodes

Aquesta tesi està formada per sis articles publicats en revistes científiques internacionals indexades en les principals bases de dades bibliogràfiques i bibliomètriques. Tot i que les principals característiques metodològiques —especialment el disseny, la mostra, els instruments, el procediment i les tècniques d'anàlisi de dades en el cas dels anomenats *estudis empírics* (American Psychological Association, 2010)— dels diferents articles es troben a bastament descrites en cadascun dels articles, en aquest apartat s'exposen els aspectes més rellevants i, entre aquests aspectes, especialment els elements comuns a cadascun dels dos blocs d'articles, blocs manifestament diferents atès l'ús de mètodes clarament diferenciats.

El primer bloc de tres articles està compost per tres estudis observacionals, de tipus transversal. Per ser més precisos, alguns autors especificarien que en el cas del segon es tracta concretament d'un estudi instrumental (Carretero-Dios i Pérez, 2005). Tots tres estudis es basen en l'anomenada *metodologia selectiva* (Anguera, 2005) o *metodologia d'enquestes per mostreig* (Trujols, 2006). Els dos primers es van fer a la ciutat de Barcelona i el tercer a la comunitat autònoma de La Rioja un cop aprovats pel Comitè Ètic d'Investigació Clínica corresponent (el de l'Hospital de la Santa Creu i Sant Pau en els dos primers casos i el de La Rioja en el tercer). En tots els casos, els participants eren pacients amb dependència dels opioides (heroïna) segons criteris DSM-IV (American Psychiatric Association, 1995), en TMM, i les avaluacions es van fer —una vegada signat el preceptiu document de consentiment informat— o bé al centre de referència de cadascun d'ells, en el cas del primer i el tercer estudi, o bé a la Unitat de Conductes Addictives de l'Hospital de la Santa Creu i Sant Pau —que també era el centre de referència d'una submostra— en el del segon estudi. El procediment de selecció dels participants en funció de l'estudi —i de l'ordre de presentació dels corresponents tres articles— va ser mitjançant mostreig exhaustiu en un únic centre, mostreig de conveniència i mostreig aleatori estratificat, respectivament. Els entrevistadors, tot i tenir una certa experiència clínica —a banda d'una àmplia expertesa en l'ús dels diferents instruments autoadministrats i heteroadministrats emprats en l'estudi—, no eren membres del personal clínic del centre de tractament. Pel que fa als principals instruments de mesura, cal destacar especialment l'Escala de Verona de Satisfacció amb el Tractament de Manteniment amb Metadona (VSSS-MT; Pérez de los Cobos et al., 2002) i les escales d'ítem únic per avaluar la perspectiva del pacient sobre: *a*) la metadona com a fàrmac per tractar la dependència de l'heroïna; i *b*) dos vessants del seu grau de participació en el procés de presa de decisions sobre la dosi de metadona (nivell d'informació rebuda sobre els canvis de dosi i grau d'influència percebuda sobre aquests canvis; Pérez de los Cobos, Trujols, Valderrama, Valero i Puig, 2005), instruments tots ells utilitzats en dos o en tots tres estudis. Així mateix, cal esmentar també els utilitzats en només un dels estudis —un en cadascun dels tres estudis—: l'Escala d'Impressió Clínica Global de Millora (CGI-I; Guy, 2004), el Qüestionari de Satisfacció amb el Tractament Farmacològic (TSQM versió 1.4; Atkinson et al., 2004) i el Qüestionari de Salut General de Goldberg (GHQ-28; Lobo, Pérez-Echeverría i Artal, 1986), respectivament i seguint l'ordre de presentació dels articles corresponents al primer bloc. Finalment, amb relació a les tècniques d'anàlisi de dades emprades, cal esmentar que en tots tres estudis, després d'estimar la taxa de resposta, s'han utilitzat en un primer moment mesures de tendència central i de dispersió per caracteritzar els participants tant des d'un punt de vista sociodemogràfic com clínic i, posteriorment, les tècniques d'anàlisi bivariable o multivariable més adequades en funció de l'objectiu de cada estudi en particular: índex kappa ponderat, coeficient de correlació de Pearson i prova Z de comparació de proporcions, en el cas del primer; anàlisis psicomètriques habituals des de la perspectiva de la teoria clàssica dels tests, en el del segon; i anàlisi de regressió lineal múltiple i anàlisi de regressió logística binària, en el del tercer i últim estudi d'aquest primer bloc.

El segon bloc de tres articles està format per tres estudis de caràcter no empíric o, seguint la normativa APA (American Psychological Association, 2010), *articles teòrics*. Tots tres, en tant que articles teòrics, han consistit en el desenvolupament fonamentat d'un argument o proposta. L'única font d'informació utilitzada ha radicat essencialment en articles de recerca, documents secundaris que, a la vegada, han esdevingut les unitats d'anàlisi. Tot i la dificultat inherent a qualsevol intent de presentació més o menys sistematitzada del procediment de col·lecció i anàlisi d'aquestes unitats, cal destacar que els documents secundaris han estat sotmesos a un procés de lectura, selecció i ordenació en funció de la nostra línia argumental, tasca de caràcter interpretatiu i eminentment comprensiva i subjectiva, és a dir, contingent i situada (Bassi, 2015). Descrit amb altres paraules, la selecció i anàlisi dels documents secundaris s'ha fet aplicant els mateixos criteris de rigor emprats habitualment a l'hora de desenvolupar el marc teòric d'un projecte d'estudi —o la introducció d'un article— empíric.

4.

Resultats

Treball 1

Trujols, J., Siñol, N., Iraurgi, I., Batlle, F., Guàrdia, J. i Pérez de los Cobos, J. (2011). Patient and clinician's ratings of improvement in methadone-maintained patients: Differing perspectives? *Harm Reduction Journal*, *8*, 23. doi:10.1186/1477-7517-8-23

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Patient and clinician's ratings of improvement in methadone-maintained patients: Differing perspectives?

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Abstract

Background: In the last few years there seems to be an emerging interest for including the patients' perspective in assessing methadone maintenance treatment (MMT), with treatment satisfaction surveys being the most commonly-used method of incorporating this point of view. The present study considers the perspective of patients on MMT when assessing the outcomes of this treatment, acknowledging the validity of this approach as an indicator. The primary aim of this study is to evaluate the concordance between improvement assessment performed by two members of the clinical staff (a psychiatrist and a nurse) and assessment carried out by MMT patients themselves.

Method: Patients (n = 110) and their respective psychiatrist (n = 5) and nurse (n = 1) completed a scale for assessing how the patient's condition had changed from the beginning of MMT, using the Patient Global Impression of Improvement scale (PGI-I) and the Clinical Global Impression of Improvement scale (CGI-I), respectively.

Results: The global improvement assessed by patients showed weak concordance with the assessments made by nurses (Quadratic-weighted kappa = 0.13, $p > 0.05$) and by psychiatrists (Quadratic-weighted kappa = 0.19, $p = 0.0086$), although in the latter, concordance was statistically significant. The percentage of improved patients was significantly higher in the case of the assessments made by patients, compared with those made by nurses (90.9% vs. 80%, Z-statistic = 2.10, $p = 0.0354$) and by psychiatrists (90.9% vs. 50%, Z-statistic = 6.48, $p < 0.0001$).

Conclusions: MMT patients' perception of improvement shows low concordance with the clinical staff's perspective. Assessment of MMT effectiveness should also focus on patient's evaluation of the outcomes or changes achieved, thus including indicators based on the patient's experiences, provided that MMT aim is to be more patient centred and to cover different needs of patients themselves.

Background

Methadone maintenance treatment (MMT) should be considered as a specific psychopharmacological treatment of heroin dependence [1] at the same time as being an essential and fundamental element of harm reduction strategies [2]. Since its introduction in heroin dependence management, MMT has undergone a constant process of review and evaluation. During the past fifteen years there have been a substantial number of systematic reviews aiming at methodically and rigorously summarising available scientific evidence on the efficacy of this treatment (e.g., [1-4]). In all these systematic reviews, efficacy and effectiveness of MMT have been evaluated almost exclusively using so-called hard indicators or criteria [5,6]: retention on the programme, abstinence from non-prescription opioids, reduced morbidity and mortality and/or reduced crime rate, among other variables. However, assessment of MMT should include patient's subjective evaluation of the treatment process and the changes achieved, by means of indicators based on their experiences [7].

At a more global level, several authors have pointed out the importance of including patient's perspective

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when assessing health technologies and health services [8,9], and the potential significance of patient's perspective towards research and generation of knowledge [10]. It should also be noted that there is a growing interest in incorporating patient's perspective in the development of clinical practice guidelines [11,12]. In fact, some of the most recent systems for establishing the strength of the recommendations (e.g., the GRADE approach [13]) include patient's preferences as one of the determinant factors: the higher the variability (i.e. uncertainty) of patients' values and preferences, the higher the probability of a weak recommendation. However, the majority of clinical practice guidelines do not include evidence on patient's preferences, particularly given the limited number of studies available on this issue [14]. Notable exceptions are the Allergic Rhinitis and Its Impact on Asthma guidelines (ARIA) [15] which include in their recommendations, suggestions such as "in many patients with strong preference for the oral versus the intranasal route of administration, an alternative choice may be reasonable" [15], p. 471.

MMT patients' perspective has received scant attention from clinicians and researchers [16,17]. Traditionally, patients' point of view has not been considered a relevant contribution to the design, implementation and evaluation of MMT. However, over the last few years there seems to be an emerging interest for including patients' perspectives in assessing MMT. This new framework is probably related to the gradual, albeit timid tendency to modify the hierarchised doctor-patient relationship based on the traditional medical model of disease, which implies a biased and exclusive perception of drug users as non-competent persons [18,19].

To date, MMT satisfaction surveys have been the most commonly-used method of incorporating patient's perspective [7]. However, other attempts have considered and explored variables such as beliefs and views about methadone [20], perceived adjustment of the methadone dose [21], assessment of the relational dynamic established with other stakeholders [22], degree of participation in decision making [21], indicators of perceived quality [23] and views on the development and improvement of MMT [24]. Assessment of MMT outcomes from patient's perspective (i.e., evaluation of global perceived improvement in comparison with the pre-MMT situation) has not received the attention it deserves. To our knowledge, only one study [25] has recently and explicitly addressed this issue but without taking into account clinician's point of view about the same outcome, nor the concordance between both perspectives.

This study considers the perspective of patients on MMT when assessing the outcomes of this treatment, acknowledging its validity as a relevant indicator. The primary aim of this study is to evaluate the concordance between improvement assessment performed by two members of the clinical staff (psychiatrists and nurses) and assessment carried out by MMT patients themselves. It also analyses whether perceived improvement by MMT patients is associated with their satisfaction with treatment and with their views on methadone as a medication for treating heroin dependence.

Method

Participants

Units of analysis in this study were 110 cases whose information was provided by three sources: 110 patients on MMT and their respective nurses and psychiatrists. Participants were methadone-maintained, opioid-dependent patients who had received MMT at our centre for at least 3 months, and who had signed an informed consent form. Each MMT patient has a psychiatrist who is responsible for their assessment, diagnosis, prescription and treatment, and a nurse in charge of monitoring and assessing patient status, handling daily medical issues and dispensing methadone. A total of five psychiatrists and one nurse participated in the study, with an average of 22 patients (range 2-46) per psychiatrist.

Instruments

To assess how the patient's condition had changed from the beginning of MMT, patients and their respective psychiatrist and nurse completed a scale: the Patient Global Impression of Improvement scale (PGI-I) and the Clinical Global Impression of Improvement scale (CGI-I) [26], respectively. These scales assess the degree in which the patient has improved in comparison with the pre-MMT situation, and consist of a single item in a 7-point Likert format (1 = very much improved to 7 = very much worse). An additional rating analysis developed by Demyttenaere et al. [27] was also used: improved (points 1 and 2), stable (points 3 to 5), and worsened (points 6 and 7). Satisfaction with MMT was assessed with the Verona Service Satisfaction Scale for Methadone Treatment (VSSS-MT) [28]. This scale has 27 items and consists of four factors: basic interventions, specific interventions, social worker skills, and psychologist skills. Items are based on a 5-point Likert scale (1 = terrible, 2 = mostly dissatisfied, 3 = mixed, 4 = mostly satisfied, 5 = excellent). The ranges of clinical significance for the VSSS-MT scores are [29]: 1-2 (very dissatisfied), > 2-3 (slightly dissatisfied), > 3-4 (slightly satisfied), and > 4-5 (very satisfied). Patients' opinion of methadone as a medication to treat heroin dependence was explored with the following question [21]: 'Taking into account your overall experience, what is your impression about methadone as a medication for carrying out maintenance treatment of heroin dependence?'.

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The same 5-point Likert scale used as a response format in the VSSS-MT (1 = terrible to 5 = excellent) is established for this question.

Procedure

The research project was approved by the Clinical Research Ethics Committee of the Hospital de la Santa Creu i Sant Pau (Barcelona, Spain). A research psychologist invited eligible patients to participate in the study and administered the surveys, which were conducted without the presence of clinical staff. No compensation was offered for participating in the study. When the clinicians completed the CGI-I scale for each patient, they were blind to patient's score on the PGI-I. The surveys were conducted between January and March 2007.

Data analysis

Quadratic-weighted kappa coefficients (κ_w) were used to express the concordance between the clinical staff's and patient's own assessment of improvement. Z tests for comparing two proportions were used to determine whether the percentage of improved patients was statistically different when comparing the assessments made by clinicians with those made by the patients themselves. Kendall's tau-b coefficients (τb) were calculated to examine the association between improvement assessed by the patient and the VSSS-MT scores or the patient's opinion of methadone as a medication. All statistical tests were two-tailed and considered significant if $p < 0.05$. Results for the quadratic-weighted Kappa coefficients and Kendall tau-b coefficients were assessed using the ranges for effect size interpretation recommended by Ferguson [30]. Statistical analyses were performed using Epidat 3.1 (Dirección Xeral de Saúde Pública de la Conselleria de Sanidade de la Xunta de Galicia and Pan American Health Organization) and SPSS Statistics 17.0 (SPSS Inc., Chicago, IL).

Results

Acceptance and completion of the survey

Although there were 120 patients on MMT at our centre at the time the study was performed, four had been on treatment for less than three months and so they were not invited to take part. Of the 116 surveys proposed, 110 (94.8%) patients agreed to participate and answered the survey. However, a psychiatrist did not complete the corresponding CGI-I scale for two patients. There were no statistically significant differences regarding the sociodemographic and clinical characteristics of the patients who refused to participate in the survey, compared with those who accepted.

Characteristics of the participants and MMT

The 110 patients who completed the survey ranged in age from 22 to 58 years, with a mean of 39.4 years (standard deviation [SD] = 6.5). Males accounted for 73.6% of the sample. With regard to marital status, 63.3% were single, 19.3% married or living with a partner, 13.8% separated or divorced and 3.7% widowed. Participants used or had used heroin intravenously (56.9%), by inhalation (18.3%) or by snorting (24.8%). The mean of patients' total MMT episodes was 1.6 (SD = 0.9, range = 1-6). Participants were taking a methadone dose of (mean ± SD) 67.2 ± 39.8 mg/d (range = 5-180). A percentage of 43.5 of patients were taking < 60 mg/d of methadone, 42.4% were taking 60-100 mg/d, and 14.1% were taking > 100 mg/d.

Relationship between patient and clinical staff assessment of improvement

Concordance between global improvement assessed by psychiatrists and nurse was moderate and statistically significant ($\kappa_w = 0.40$, 95% Confidence Interval [CI] = 0.26-0.55, $p < 0.0001$). However, the global improvement assessed by patients showed low concordance with the assessments made by nurse ($\kappa_w = 0.13$, 95% CI = -0.05-0.31, $p > 0.05$; Table 1) and psychiatrists ($\kappa_w = 0.19$, 95% CI = 0.08-0.30, $p = 0.0086$; Table 2), although the latter value reached statistical significance.

By recoding scores of PGI-I and CGI-I into three categories (improved, stable and worsened) [27], the percentage of improved patients was significantly higher in the case of the patients' own assessments compared with those made by nurse (90.9% vs. 80%, 95% CI for the difference between proportions = 0.01-0.21, Z-statistic = 2.10, $p = 0.0354$) and psychiatrists (90.9% vs. 50%, 95% CI for the difference between proportions = 0.29-0.53, Z-statistic = 6.48, $p < 0.0001$).

Relationship between patient-assessed improvement and their satisfaction with MMT

The global score in the VSSS-MT was (mean ± SD) 3.8 ± 0.5, and VSSS-MT factor scores were as follows: 3.9 ± 0.6 in basic interventions, 3.5 ± 0.7 in specific interventions, 3.5 ± 1.0 in social worker skills, and 3.9 ± 0.9 in psychologist skills. All these scores indicated 'slight satisfaction' according to the VSSS-MT ranges of significance [29]. No statistically significant association was found between perceived improvement by MMT patients and their satisfaction with treatment. With regard to overall VSSS-MT score and factors, the Kendall tau-b values ($-0.12 < \tau b < 0.09$) did not reach statistical significance (Table 3).

Table 1 Concordance between patient and nurse perceptions of improvement

		Patient Global Impression of Improvement (PGI-I) scale							
		Very much improved	Much improved	Minimally improved	No change	Minimally worse	Much worse	Very much worse	Total
Clinical Global Impression of Improvement (CGI-I) scale	**Very much improved**	61	12	1	1			2	77
	Much improved	8	2		1				11
	Minimally improved	4	2	1		1	1		9
	No change	4	4	1	1				10
	Minimally worse	1							1
	Much worse	1							1
	Very much worse	1							1
	Total	80	20	3	3	1	1	2	110

Data expressed as frequencies.

Relationship between patient-assessed improvement and patient's opinion of methadone as a medication

Although most participants had an excellent (27.3%) or mostly satisfied (56.4%) opinion of methadone as a medication for treating opioid dependence, almost a sixth of the participants expressed an opinion that was mixed (10.9%), mostly dissatisfied (1.8%) or terrible (3.6%). A statistically significant but weak association was found between perceived improvement by patients on MMT and their opinions of methadone as a medication (τb = -0.18, p = 0.042, Table 3). In fact, this correlation lost its statistical significance when patient-perceived improvement was classified by just three categories (improved, stable and worsened) [27]: τb = -0.13, p > 0.05.

Discussion

The primary objective of this study was to assess the concordance between the assessment of improvement evaluated by two members of clinical staff (a psychiatrist and a nurse) and the assessment performed by MMT patients themselves. The results reveal that global improvement assessed by patient showed low concordance with nurse- and psychiatrist-assessments. It has to be mentioned that although patient-psychiatrist concordance reached statistical significance, it did not meet the recommended minimum effect size [30]. This low concordance between clinical staff's and patient's perspective stems from the fact that patients' assessments are significantly more frequently positive. This patient-clinician discrepancy regarding perceived improvement is

Table 2 Concordance between patient and psychiatrist perceptions of improvement

		Patient Global Impression of Improvement (PGI-I) scale							
		Very much improved	Much improved	Minimally improved	No change	Minimally worse	Much worse	Very much worse	Total
Clinical Global Impression of Improvement (CGI-I) scale	**Very much improved**	29	4						33
	Much improved	15	5	1					21
	Minimally improved	21	4			1	1	2	29
	No change	8	4	2	2				16
	Minimally worse	4	1						5
	Much worse	1	2						3
	Very much worse				1				1
	Total	78	20	3	3	1	1	2	108

Data expressed as frequencies.

Table 3 Kendall's tau-b correlations of PGI-I with VSSS-MT scores and opinion of methadone as a medication

	PGI-I
VSSS-MT, overall	-0.032
VSSS-MT, Basic interventions	-0.001
VSSS-MT, Specific interventions	-0.063
VSSS-MT, Social worker skills	-0.106
VSSS-MT, Psychologist skills	0.088
Opinion of methadone as a medication	-0.178*

VSSS-MT: Verona Service Satisfaction Scale for Methadone Treatment; PGI-I: Patient Global Impression of Improvement scale; *$p < 0.05$, two-tailed. The scores on the PGI-I scale are in descending order of improvement (1 = very much improved to 7 = very much worse) while both the VSSS-MT and the scores on the opinion on methadone as a medication are in increasing order of satisfaction (1 = terrible to 5 = excellent).

consistent with the results of the study conducted by Pulford et al. [31] comparing client (new admissions to an alcohol and other drug counseling community-based service) and clinician perspectives on problem improvement at two months of follow-up. Similarly, the main results of this study showed that clinician ratings of client improvement were significantly lower than ratings the clients gave themselves [31]. This patient-clinician discrepancy regarding patient improvement is also quite common, although not unanimous, in the field of mental health (see [32] for a review).

A first possible explanation for this patient-clinician discrepancy regarding the assessment of MMT results could lie in the fact that patients may have a tendency to assess their progress more positively. This tendency would in turn be explained by one of the following facts or possibilities, which are not mutually exclusive: a) patients have a more detailed knowledge of their situation before starting MMT and of their current condition and changes in relation to the previous situation, b) some clinicians may be too strict or demanding when allocating certain scores, c) some patients aware of their limited or lack of improvement, could overrate the improvement in order to reduce their cognitive dissonance.

An alternative explanation for the patient-clinician discrepancy regarding the assessment of MMT results could stem from the fact that clinicians and patients emphasise different areas and outcomes when they define success, progress or improvement. This definition would largely depend on how MMT is conceptualised and what goals have been set for this treatment. As Koester et al. [33] showed, there are many different goals or reasons for a heroin user to enter and/or stay on MMT and they may differ from those of the professionals who provide these treatments. In turn, these professionals also have a wide range of beliefs and attitudes about the goal of MMT [34]. However, all too often the goal of MMT is not negotiated and agreed with patient [35,36], implicitly and naively assuming that both the goal and, consequently, the definition of improvement are the same for the patient and clinician. Despite this assumption, a considerable number of authors (e.g., [7,33,37-39]) point out the need to consider patients' priorities when a) rethinking what is understood by a successful MMT or intervention, and b) establishing areas and outcomes that need to be assessed when establishing the effectiveness of these interventions. In fact, within some harm reduction services or programs, models and instruments to assess outcomes have been developed that are consistent with the fact that both the concepts of success and progress and their assessment should be reformulated in order to reflect the patient's perspective (e.g., [40,41]).

Another notable finding of the present study is that MMT patients' perceived improvement is not associated with their satisfaction with MMT or with their views on methadone as a medication. These findings are consistent with previous results on a sample of patients on MMT by Perreault et al. [25] and by Ries et al. [42] in a study based on a sample of dually diagnosed outpatients participating in a long-term integrated dual disorder treatment. Correlational analyses of Perreault et al. [25] between several measures of perceived improvement and satisfaction with MMT revealed both non-significant associations and some statistically significant but weak correlations. All in all, these results seem to show that satisfaction with MMT is weakly related to the treatment outcome when assessed from patient's perspective. Therefore, it could be suggested that these two variables, though slightly related, represent distinct approaches to MMT patient's perspective. In this regard, a study by Rademakers et al [43] found that, when exploring the extent to which satisfaction aspects determine patients' overall satisfaction rating, aspects related to process were the most important predictors of this global rating, followed by aspects of structure and, lastly, aspects of outcome.

This study is not without limitations. Its cross-sectional design does not permit causal relationships to be established between the different variables related to the patient's perspective. Although the sampling was exhaustive, the fact that patients and clinicians were from a single MMT centre, limits the generalisability of these findings to other MMT programs. Since both the PGI-I scale and the CGI-I scale are generic single-item tools, the detail of information obtained from these scales is somewhat limited. Moreover, due to the fact that both scales do not specify criteria for assessing the change experienced by patients with regard to their condition before starting MMT, it cannot be assured whether patients and clinicians have been guided by the same outcome areas and goals when assessing this change. However in the case of the PGI-I scale, this very fact may have increased the relevance, significance or content validity of a scale developed by clinicians without the participation of patients themselves. Despite these limitations, the fact that parallel versions of the same scale (i.e., PGI-I and CGI-I) were used in this study to assess MMT patients' improvement, reinforces the robustness of the low concordance between patients and clinical staff when rating perceived improvement of MMT patients, found in this study.

Further research is needed not only to assess the generalisability of these findings to patients and clinicians from other MMT programs and/or geographic areas, but also to provide new data about patient-clinician concordance regarding MMT outcomes by including additional instruments for a deeper assessment of the matter. Moreover, future studies should also provide evidences, through qualitative research methods such as focal groups, in-depth interviews or cognitive interviews, about the outcome domains and/or variables that both patients and clinicians consider in assessing patient's improvement.

Conclusions

MMT patients' perception of improvement shows low concordance with the clinical staff's perspective. Assessment of MMT efficacy and effectiveness should also take into account patient's evaluation of the outcomes or changes achieved. Therefore, indicators based on the patient's experiences should be included, provided that MMT aim is to be more patient centred and to cover different needs of patients themselves.

Abbreviations

CGI-I: Clinical Global Impression of Improvement scale; 95% CI: 95% Confidence Interval; MMT: methadone maintenance treatment; PGI-I: Patient Global Impression of Improvement scale; SD: standard deviation; VSSS-MT: Verona Service Satisfaction Scale for Methadone Treatment.

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Authors' contributions

JT and JP designed the study and wrote the protocol. JT and NS managed the literature searches and summaries of previous related work. Data collection was done by FB and NS. JT, II and JG designed the analysis plan. JT and II undertook the statistical analysis. All authors participated in the interpretation of findings. JT wrote the first draft of the manuscript. All authors contributed to and have approved the final version submitted for publication.

Competing interests

The authors declare that they have no competing interests.

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Treball 2

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ORIGINAL CONTRIBUTION

Satisfaction With Methadone as a Medication

Psychometric Properties of the Spanish Version of the Treatment Satisfaction Questionnaire for Medication

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Abstract: There is a manifest lack of psychometrically sound instruments designed for specific and multidimensional assessment of satisfaction with methadone as a medication within the context of methadone maintenance treatment. Therefore, it may be worthwhile to assess the pertinence and utility of using a generic and multidimensional medication satisfaction instrument that has not been specifically developed for use in methadone maintenance treatment.

The aim of this study was thus to explore the psychometric properties of the Spanish version of the Treatment Satisfaction Questionnaire for Medication (TSQM version 1.4 [*Health Qual Life Outcomes*. 2004;2:12]) in a sample of methadone-maintained heroin-dependent patients.

Two hundred three methadone-maintained patients filled out the TSQM and other several measures related to the construct of patient satisfaction (eg, Verona Service Satisfaction Scale for methadone treatment). Dimensionality of the TSQM was assessed by means of a confirmatory factor analysis. Internal consistency was examined using the ordinal coefficient α. Spearman correlations were used to explore the relationship between the TSQM and the measures conceptually related to patient satisfaction.

Regarding the dimensionality of the TSQM, its original factor structure adequately fitted the data (Satorra-Bentler χ^2_{58}, 72.14 [$P = 0.100$]; root-mean-square error of approximation, 0.045; comparative fit index, 0.978). All but 1 of the 4 TSQM subscales showed acceptable to good internal consistency values (0.78–0.89). The dimensions of the TSQM were differentially and congruently correlated with related measures.

The results strongly suggest the TSQM value as a brief, generic, and psychometrically sound instrument to assess satisfaction with methadone as a medication in a multidimensional manner. Notwithstanding, more research is needed not only to assess the generalizability of these findings but also to provide pieces of evidence for other psychometric properties, especially the TSQM predictive validity.

Key Words: methadone maintenance treatment, satisfaction with medication, Treatment Satisfaction Questionnaire for Medication, psychometric analyses, opioid dependence, patient-reported outcomes

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The meanings attached to the construct of patient satisfaction—and their operationalizations—within the context of a methadone maintenance treatment (MMT) may lead to some degree of fuzziness and confusion. From both research and clinical perspectives, it seems necessary to distinguish among holding dose, dose adequacy, satisfaction with methadone as a medication, and satisfaction with treatment, despite their interrelated nature and overlapping specificities.[1] Although the processes of assessment of 3 of these constructs (ie, holding dose, dose adequacy, and satisfaction with MMT) have been widely addressed, satisfaction with methadone as a medication has not got a particular instrument. In this regard, holding status can be determined by several specific approaches.[2,3] The adequacy of a methadone dose can also be evaluated by means of a tool, the Opiate Dosage Adequacy Scale.[4,5] Patient satisfaction with MMT can also be assessed specifically with the Verona Service Satisfaction Scale for methadone treatment (VSSS-MT)[6] or with generic instruments designed to measure treatment satisfaction in the substance-abuse treatment area[7] or in general.[8] On the contrary, there is a paucity of approaches designed to assess satisfaction with methadone as a medication in particular. In the rare occasions when satisfaction with methadone as a medication has been measured, the assessment involves a single question addressing overall satisfaction (eg, Pérez de los Cobos et al[9]). These single-item and global measures of satisfaction with methadone as a medication limit overmuch the nuances of a variable—satisfaction with medication—that is essentially multidimensional.[10,11]

The lack of specific instruments designed for the assessment of satisfaction with medication within the context of MMT, taking into account the multidimensionality of the construct, is particularly surprising when we consider both that patient satisfaction with medication is an important patient-reported outcome[11] and that several instruments are available to measure other types of patient's beliefs and attitudes about methadone.[12–15] Moreover, research on other medical conditions shows that patients' satisfaction with their medication is positively associated with both treatment adherence and health outcomes.[16–19]

It seems thus important to evaluate satisfaction with methadone as a medication using psychometrically sound instruments that can deliver accurate measures in clinical trials and practice, provided that such a concept is multidimensional. To develop ex novo an instrument to assess satisfaction with methadone as medication would represent huge efforts. Thus, before undertaking such a task, one possibility could be to ascertain the pertinence and utility of using a generic and multidimensional

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instrument that has not been developed for use in MMT. As a step in this direction, the aim of this study was to explore the psychometric properties of the Spanish version of the Treatment Satisfaction Questionnaire for Medication (TSQM version 1.4),[17] a psychometrically robust and widely used[20–22] generic measure of satisfaction with medication, in a sample of methadone-maintained patients. The following 3 measurement properties were addressed: dimensionality, internal consistency, and relationship with other variables related to the construct of patient satisfaction. Regarding the latter, the following 3 hypotheses were particularly examined: (*a*) Scores in the TSQM would positively correlate with a single-item measure addressing overall satisfaction with methadone as a medication.[9] (*b*) Scores in the TSQM would positively correlate with satisfaction with MMT (measured with the VSSS-MT).[6] This hypothesis stands on the fact that satisfaction with MMT is a broader construct involving more than just satisfaction with methadone as a medication.[1] (*c*) Scores in the TSQM would positively correlate with a 2-item measure addressing perceived participation in decision-making on methadone dose.[9] The latter is based on previous studies that have shown that substance-abuse patients who were more involved in their treatment were more likely to be satisfied.[23]

METHODS

Participants

Participants were methadone-maintained, heroin-dependent patients who had received MMT at their respective centers for at least 3 months and who had signed an informed consent form. Accidental sampling was used; potential participants were invited to participate in the study because of their ready availability and convenience (MMT patients recruited from both outpatient and inpatient facilities of Santa Creu i Sant Pau Hospital at Barcelona, Spain). Likewise, the heterogeneity of the participants in several variables was purposely reflected (eg, MMT patients stabilized on a wide range of methadone doses, MMT patients taking methadone as an oral solution or in tablet form, MMT patients admitted to an inpatient detoxification unit to discontinue MMT, and MMT patients undergoing inpatient detoxification from nonopioid substances while they continued methadone treatment).

Assessments

Satisfaction With Methadone as a Medication

Patient satisfaction with methadone as a medication was assessed with the TSQM (version 1.4).[17] The TSQM is a 14-item self-reported generic instrument designed to measure patient satisfaction with medication treatment. The 4 scales of the TSQM include the Effectiveness subscale (items 1–3), the Side Effects subscale (items 4–8), the Convenience subscale (items 9–11), and the Global Satisfaction subscale (items 12–14). The last subscale is regarded both in concept and in research as a superordinate, second-order global factor encompassing the other 3 more specific domains of medication experiences.[17] Responses are obtained on a 5-point or a 7-point Likert scale (range, 1 "extremely dissatisfied" to 7 "extremely satisfied") for all but 1 item that has a yes-no response option. The subscale scores are transformed into scores ranging from 0 to 100, with higher scores representing higher satisfaction on that domain. Regarding the Side Effects subscale, when the patient answers "no" to experiencing side effects (item 4), this subscale is scored as 100. Permission to use the Spanish version of the TSQM 1.4 was granted by Quintiles, Inc (Durham, NC). A copy of the English and Spanish versions of the questionnaire, reproduced by permission of the copyright holder (Quintiles, Inc), can be seen as a supplemental material (Supplemental Digital Content 1, http://links.lww.com/JCP/A112).

The opinion of patients regarding methadone as a medication for treating heroin dependence was also explored with the question,[9] "Taking into account your overall experience, what is your impression about methadone as a medication for carrying out maintenance treatment of heroin dependence?" Response options were as follows: 1, terrible; 2, mostly dissatisfied; 3, neither dissatisfied nor satisfied; 4, mostly satisfied; and 5, excellent.

Satisfaction With MMT

Patient satisfaction with MMT was assessed with the VSSS-MT.[6] The VSSS-MT is a self-reported 27-item scale comprising 4 factors: Basic Interventions (15 items), Specific Interventions (8 items), Social Worker Skills (2 items), and Psychologist Skills (2 items). Basic Interventions mainly assesses physicians' and nurses' skills and the help received in improving social relationships and self-care. Specific Interventions assesses only psychosocial interventions. All items have a 5-point Likert scale response option as follows: 1, terrible; 2, mostly dissatisfied; 3, neither dissatisfied nor satisfied; 4, mostly satisfied; and 5, excellent. On items referring to professional manner or activities, the participants also have the response option of "not applicable." The VSSS-MT scores are obtained by averaging applicable items; the range of total score and subscores on the VSSS-MT is 1 to 5.

Perceived Participation in Decision-Making on Methadone Dose

Following Pérez de los Cobos et al,[9] patients' involvement in MMT was explored by means of 2 questions. Information regarding changes in methadone dose was assessed with the question, "Are you informed about the changes your center's staff makes with regard to your methadone dose?" Response options were as follows: 1, never; 2, very rarely; 3, sometimes; 4, almost always; and 5, always. Perceived influence on methadone dose changes was ascertained with the question, "Do you think that your opinion influences your center's staff to modify the methadone dose you take?" The 5-point Likert scale response option to this question was as follows: 1, no; 2, a little; 3, somewhat; 4, quite a lot; and 5, a great deal.

Procedure

The research project was approved by the clinical research ethics committee of Santa Creu i Sant Pau Hospital (Barcelona, Spain). A research assistant invited eligible patients to participate in the study and guided the participants through instructions for all instruments, answered their questions regarding scales completion, and stayed through the assessment session until all items were filled out. All instruments were administered individually in a single session and without the presence of clinical staff. No compensation was offered for participating in the study.

Data Analysis

With regard to the dimensionality of the TSQM scale, on the basis of both the conceptual framework underlying its development and the findings of previous research with this scale, 5 hypothesized structures were tested by means of confirmatory factor analysis (CFA).

TABLE 1. Fit Indices for the TSQM Models Tested Via CFA

Model	SB-χ^2	*df*	*P*	AIC	RMSEA (90% CI)	NNFI	CFI	IFI
1. Single factor	165.80	65	<0.001	35.80	0.113 (0.091–0.133)	0.809	0.841	0.844
2. Four uncorrelated factors	176.64	65	<0.001	46.64	0.119 (0.097–0.139)	0.788	0.824	0.827
3. Four correlated factors	75.35	59	0.074	−42.64	0.048 (0.000–0.077)	0.966	0.974	0.975
4. Four factors and 1 second-order factor	74.99	60	0.092	−45.00	0.045 (0.000–0.075)	0.969	0.976	0.977
5. Three factors and 1 second-order factor	72.14	58	0.100	−43.85	0.045 (0.000–0.075)	0.970	0.978	0.978

AIC indicates Akaike information criteria; CFI, comparative fit index; CI, confidence interval; IFI, Bollen incremental fit index; NNFI, Bentler-Bonett non-normed fit index; RMSEA, root-mean-square error of approximation; SB-χ^2, Satorra-Bentler χ^2.

Given the nature of all TSQM items (Likert-scaled, nonnormally distributed data), the CFA was conducted on the polychoric correlation matrix using the robust maximum likelihood estimation method. Goodness of fit was evaluated by means of the following robust indices: the Satorra-Bentler[24] χ^2 and Yuan-Bentler[25] χ^2 (YB-χ^2) statistics, the Akaike information criteria,[26] the root-mean-square error of approximation and its 90% confidence interval,[27] the Bentler-Bonett non-normed fit index,[28] the comparative fit index,[29] and the Bollen incremental fit index.[30] Nonsignificant Satorra-Bentler χ^2 and YB-χ^2; a root-mean-square error of approximation of 0.06 or lower; and values of 0.95 or higher for the Bentler-Bonett non-normed fit index, comparative fit index, and Bollen incremental fit index suggest an adequate fit of the model to the data.[31,32] The Akaike information criterion measure indicates that the smaller the value, the better the fit is. Model comparisons were conducted using the YB-χ^2 difference test.[33]

The reliability as internal consistency of each of the subscales of the TSQM was calculated using the ordinal coefficient α.[34] Spearman rank-order correlations were used to explore the relationship between the TSQM subscales and the other measures related to the construct of patient satisfaction. All statistical tests were 2-tailed and considered significant if $P < 0.05$. The statistical analyses were performed using SPSS Statistics 17.0 (SPSS, Inc, Chicago, Ill) and EQS 6.1 (Multivariate Software, Inc, Encino, Calif).

RESULTS

Characteristics of the Participants

Although 242 MMT patients were invited to participate in the study, 39 (16.1%) patients refused to participate and/or did not complete the scales. There were no statistically significant differences regarding sociodemographic and clinical characteristics of the patients who refused to participate in the study, compared with those who accepted (data not shown).

The study sample included 203 patients, ranging in age from 23 to 61 years, with a mean (SD) of 39.8 (6.6) years. Males accounted for 74.4% of the sample. Regarding marital status, 62.1% were single, 18.7% were married or living with a stable partner, 15.8% were separated or divorced, and 3.4% were widowed. The participants used or had used heroin intravenously (64.5%), intrapulmonarily (14.8%), or intranasally (20.7%). The mean (SD) of patients' total MMT episodes was 1.9 (1.3) (range, 1–10), and the mean (SD) duration of the current treatment episode was 51.6 (51.1) months (range, 3–214 months). The participants were taking a mean methadone dosage of 69.0 (65.5) mg/d (range, 2–380 mg/d) and had been on their current

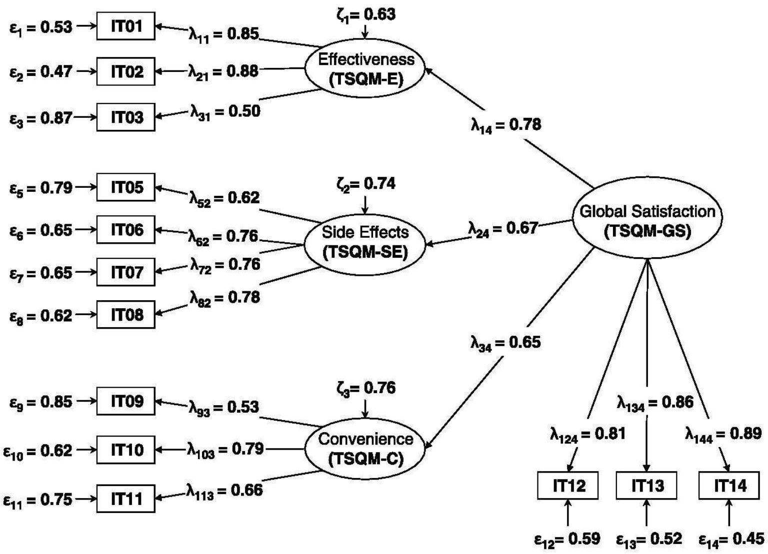

FIGURE 1. Completely standardized parameter estimates for the TSQM original structure.

TABLE 2. TSQM Subscales Internal Consistency, Means, and SDs

TSQM Subscales	Ordinal Coefficient α	No. Items	Mean	SD	Floor Effect, %	Ceiling Effect, %
Effectiveness	0.776	3	67.0	16.6	0.5	3.4
Side Effects	0.819	4	70.3	29.0	2.0	39.4
Convenience	0.693	3	63.6	15.8	0.5	3.0
Global Satisfaction	0.888	3	59.4	23.6	3.0	5.4
TSQM total	0.892	13	65.1	16.2	0.5	1.0

dose for 367.1 (635.3) days (range, 3–4810 days). Of the patients, 52.2% were taking less than 60 mg/d of methadone, 31.5% were taking 60 to 100 mg/d, and 16.3% were taking more than 100 mg/d. The daily methadone dose was administered in the form of an oral solution in 62.6% of the sample and in tablets for the rest.

Dimensionality of the TSQM

Five competing models of the latent structure of the TSQM were tested by means of CFA. Model 1 hypothesized a single general factor on which all the TSQM items were loaded. Model 2 posited a structure of 4 uncorrelated factors (the 4 original TSQM subscales). Model 3 specified a structure of 4 correlated factors (the same 4 original TSQM subscales). Model 4 hypothesized a second-order general factor that accounts for the relationships among the 4 factors (the same 4 original TSQM subscales). Model 5, representing the original structure of the TSQM,[17] posited a second-order global factor (the original Global Satisfaction subscale of the TSQM), with its respective 3 indicators or items, that accounts for the relationships among the 3 first-order factors (the original Effectiveness, Side Effects, and Convenience subscales of the TSQM). The results from the CFA, summarized in Table 1, indicate that both models 1 and 2 resulted in a similar poor fit. On the contrary, models 3 to 5 are 3 models that fitted the data satisfactorily. Indeed, all their fit indices point to a strong model fit. Drawing from their respective YB-χ^2 statistics (model 3: YB-$\chi^2_{59} = 58.38$, $P = 0.498$; model 4: YB-$\chi^2_{60} = 58.10$, $P = 0.545$; model 5: YB-$\chi^2_{58} = 55.89$, $P = 0.554$), the results of the 3 YB-χ^2 difference tests indicate that the 3 models do not differ significantly in their fit to the data: model 3 versus model 4: ΔYB-$\chi^2_1 = 0.28$, $P = 0.596$; model 3 versus model 5: ΔYB-$\chi^2_1 = 2.49$, $P = 0.114$; and model 4 versus model 5: ΔYB-$\chi^2_2 = 2.21$, $P = 0.331$.

Figure 1 depicts model 5, selected among the equally fitting models 3 to 5 for being the original structure of the TSQM.[17] All factor loading (λ coefficients) values were positive, statistically significant ($P < 0.05$), and in the fair to excellent range.[35]

Reliability of the TSQM

Table 2 shows ordinal coefficient α for the different TSQM subscales. All but one of the ordinal α values exceeded the commonly used threshold of acceptable level of internal consistency (0.70).[36] The only exception was the Convenience subscale whose ordinal coefficient α was marginally less than the threshold value required for an acceptable reliability. Table 2 also shows the means and SDs for each of the 4 TSQM subscales and for the total score of the TSQM. The mean values on the different TSQM factors fell within the range of intermediate values of each subscale. As shown also in Table 2, only the Side Effects subscale had a ceiling effect higher than 5%.

TSQM Validity Evidences Based on the Association With Other Variables

As hypothesized, statistically significant positive correlations were found between the TSQM subscales and several measures related to patient satisfaction (Table 3). All TSQM subscales were positively correlated with the single-item and global measure of satisfaction with methadone as a medication. Likewise, both Effectiveness and Side Effects dimensions were positively correlated with both the VSSS-MT Basic Interventions and Specific Interventions subscales. Convenience dimension was also positively correlated with the VSSS-MT Specific

TABLE 3. Spearman Rank-Order Correlations for the Relationship Between the TSQM Subscales and Conceptually Related Constructs

	TSQM				
Scales	Effectiveness	Side Effects	Convenience	Global Satisfaction	TSQM Total
VSSS-MT					
Basic interventions	0.34*	0.18†	0.14	0.33*	0.31*
Specific interventions	0.36*	0.27‡	0.33*	0.28‡	0.36*
Social worker skills	0.02	−0.02	0.07	0.10	0.06
Psychologist skills	0.25‡	−0.10	0.07	0.19	0.12
VSSS-MT, overall	0.38*	0.19†	0.23‡	0.35*	0.35*
One-item questions					
Satisfaction with methadone	0.59*	0.32*	0.32*	0.72*	0.64*
Information about dose changes	0.12	0.12	0.16†	0.20‡	0.21‡
Influence on dose changes	0.13	0.04	0.20‡	0.17†	0.16†

*$P < 0.001$, 2-sided.

†$P < 0.05$, 2-sided.

‡$P < 0.01$, 2-sided.

Interventions subscale. Regarding the 2 questions addressing patients' participation in decision-making on methadone dose, both the Convenience and the Global Satisfaction subscales of the TSQM were positively correlated with both.

DISCUSSION

The aim of this study was to explore the psychometric properties of a generic measure of patients' satisfaction with their medication, the TSQM, in a sample of methadone-maintained patients. Taken together, the results reveal that the TSQM shows satisfactory metric properties.

Regarding the dimensionality of the TSQM, both its original factor structure and 2 similar alternatives show a good fit according to all of the indices used. When looking at the results, the original factor structure has a marginal superior fit although it is not the most parsimonious model. Considering that the Global Satisfaction subscale was originally conceptualized as a superordinate second-order factor,[17] the results of this study can be interpreted both as strongly supporting the adequacy of the original factor structure of the TSQM and as favoring such a solution over other equally fitting models.

As to the internal consistency of the instrument, the reliability estimates of all but one of the subscales show acceptable to good values, especially considering the reduced number of items per subscale. These values are, however, slightly lower than those reported by Atkinson et al[17] when describing the TSQM development process. The marginally low ordinal coefficient α of the Convenience subscale suggests that its 3 items, in the context of a methadone maintenance program, could be a less homogeneous measure than intended. Floor and ceiling effects of all but one of the subscales are negligible. The high-ceiling effect of the Side Effects subscale can be considered a measure artifact owing to its correction algorithm (this subscale should be scored with its maximum score when the patient answers no to experiencing side effects). Indeed, the ceiling effect of this subscale decreases dramatically (from 39.4% to 0%) when the analysis is limited to patients experiencing side effects from methadone.

The results obtained from the relationship between the TSQM subscales and several measures related to patient satisfaction are consistent with the hierarchical structure of variables related to the construct of patient satisfaction in the context of an MMT.[1] The correlation of the TSQM, both the total composite score and the subscales, with the single-item and global measure of satisfaction with methadone as a medication is particularly high. The effect sizes of the correlations between the TSQM and the VSSS-MT are substantially higher for the VSSS-MT subscales that are more related to the pharmacological side of MMT.[6] The significant but low correlations between the Convenience and Global Satisfaction TSQM subscales and the 2 single-item measures of patients' participation in dosage decisions are consistent with the positive association between substance-abuse patients' participation in and satisfaction with the treatment.[23]

The main limitations of this study are (*a*) the array of measures used to provide TSQM validity evidences (based on its association with other variables) that might be slightly restrained and (*b*) the accidental sampling method, a recruitment procedure that does not ensure representativeness of MMT patients. Therefore, further research is needed not only to assess the generalizability of these findings to patients dependent on prescription opioids undergoing MMT or to patients on MMT from other programs (eg, with a substantially different mean methadone dose) and/or geographic areas but also to provide new pieces of evidence of validity by including a wider range of self-report measures of different variables theoretically linked to patient satisfaction. Moreover, future studies should also provide pieces of evidence for other psychometric properties, especially the TSQM predictive validity.

In summary, the results of this study show the TSQM value as a brief, generic, and psychometrically sound instrument to assess satisfaction with methadone as a medication from a multidimensional perspective both in research and in clinical settings.

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AUTHOR DISCLOSURE INFORMATION

Joan Trujols declares receiving consulting honoraria from Roche. Víctor Pérez has acted as a consultant, received grants, or acted as a speaker in activities sponsored by the following companies: AstraZeneca, Boehringer-Ingelheim, Eli Lilly and Company, Lundbeck, Pfizer, and Sanofi-Aventis. José Pérez de los Cobos declares both having received grant support for clinical research or educational activities from Eli Lilly and Company, Esteve, Janssen-Cilag, and Schering-Plough and receiving consulting honoraria from Roche. The rest of the authors declare no financial interests or potential conflicts of interest related directly or indirectly to this article.

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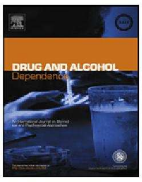

Patient satisfaction with methadone maintenance treatment: The relevance of participation in treatment and social functioning

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ABSTRACT

Background: Patients' satisfaction with methadone maintenance treatment (MMT) is a key measure of treatment quality. The main objective of the present study is to identify independent factors that contribute significantly to satisfaction with MMT.
Method: Participants were a representative sample of methadone-maintained patients ($n = 123$) from the region of La Rioja. Satisfaction with MMT was assessed with the Verona Service Satisfaction Scale for Methadone Treatment (VSSS-MT), and mental health status with the General Health Questionnaire-28 (GHQ-28). Multivariate linear- and logistic-regression analyses were performed to identify variables independently associated with satisfaction with MMT.
Results: Multiple linear regression analysis revealed that the variables independently associated with VSSS-MT total score were number of hours per week that the centre dispensed methadone ($\beta = 0.193$), number of patients per centre ($\beta = 0.233$), perceived frequency of receiving information about methadone dose changes ($\beta = 0.246$), perceived influence on these changes ($\beta = 0.194$), and Social Dysfunction subscale of GHQ-28 ($\beta = -0.179$). Multivariate binary logistic regression showed that the variables independently associated with the likelihood of being satisfied with MMT were number of years of education completed (OR = 0.835), number of patients per centre (OR = 1.009), perceived frequency of receiving information about methadone dose changes (OR = 1.571), and Social Dysfunction subscale of GHQ-28 (OR = 0.748).
Conclusions: Patients from larger centres, who perceive themselves as participating to some extent in treatment decisions, and showing lower deterioration in social functioning are more likely to be satisfied with MMT.

1. Introduction

For several decades, the European policy priorities in the field of substance abuse were focused on creating large networks of diversified social and health care services. By contrast, the current policies are directed to ensure a quality care, tailored to the user needs, for all people with drug-related problems (Delegación del Gobierno para el Plan Nacional sobre Drogas, 2009; Escuela Andaluza de Salud Pública et al., 2004; European Monitoring Centre for Drugs and Drug Addiction, 2010). Introducing the patient's perspective in evaluating health services has received increasing attention in health and social care quality improvement strategies (Bridges and Jones, 2007; Facey et al., 2010; Gagnon et al., 2009; Oliver et al., 2001). In fact, the assessment of heroin-dependent patient satisfaction with methadone maintenance treatment (MMT) has been highly recommended to improve quality of services provided by these treatment programmes (Bell, 2000; Marsden et al., 2000; Trujols and Pérez de los Cobos, 2005). Prior research has established the importance of patient satisfaction as a predictor of MMT retention (Kelly et al., 2010, 2011; Villafranca et al., 2006), a non-trivial finding taking into account that tenure in MMT is a necessary but not sufficient condition for positive treatment outcomes (Zhang et al., 2003).

Services provided by community-based mental health centres and their staff composition have much in common with methadone treatment centres. This was the main reason why the Verona

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Service Satisfaction Scale (VSSS; Ruggeri et al., 1996, 2000) was considered the most logical and best starting-point for developing an instrument to specifically assess heroin-dependent satisfaction with MMT (i.e., the VSSS for Methadone Treatment (VSSS-MT); Pérez de los Cobos et al., 2002).

To consider the mental health status of methadone-maintained patients is a key factor that influences health authorities' decisions about the most appropriate care and services that should be provided by methadone treatment centres. Indeed, it may be hypothesized that the dissatisfaction with MMT reported by several patients is partly explained by higher levels of psychopathological symptoms, because patients with such symptoms may consider that one of their core needs has been insufficiently met by current MMT. In support of this hypothesis, an association between high levels of psychopathology and low patient satisfaction with primary (Desai et al., 2005) and hospital (Hoff et al., 1999) health care has been reported. Moreover, the methadone-maintained patients' need of being treated for potential psychiatric comorbidity may not be sufficiently covered in Spain, since public MMT centres are not integrated into the Spanish Public Mental Health System. However, a high but variable proportion (44–78%) of methadone-maintained patients suffer from comorbid psychiatric disorders, mainly mood, anxiety and personality disorders (Astals et al., 2009; Brooner et al., 1997; Carpentier et al., 2009; Strain et al., 1991; Wedekind et al., 2010).

Despite the relevance of a potential association between mental health status and satisfaction with MMT, to date there is a manifest lack of studies addressing this issue. Therefore, the main objective of the present study is to identify independent factors that contribute significantly to satisfaction with MMT, hypothesizing in particular that higher levels of psychopathological symptoms will be independently associated with lower satisfaction with MMT.

2. Method

2.1. Setting and participants

Participants were methadone-maintained, heroin-dependent patients (DSM-IV: 304.02) who had received MMT at their respective centres for at least 3 months. In order to obtain a representative sample, the Drug Co-ordinator of La Rioja provided us with the list of both all regionally funded methadone treatment centres and all methadone-maintained patients (identified by an anonymised identification code) treated at each one. There was, in October 2006, a total of 4 non-prison methadone treatment centres (all of the 10 pharmacies were considered to constitute a single centre) that dispensed methadone to 327 opioid-dependent patients. On the basis of this population's size, and given a previous estimate of 15.9% of patients dissatisfied (Pérez de los Cobos et al., 2004), a sample size of 127 would be required to estimate the 95% CI of the proportion of satisfied patients with an accuracy of plus/minus 0.05. However, assuming a non-response rate of 26.7% (Pérez de los Cobos et al., 2004), the final sample size was set at 174 MMT patients. A stratified random sampling procedure was used to select potential participants, taking into account both the gender distribution and the total number of patients per centre.

2.2. Measures

2.2.1. Satisfaction with methadone maintenance treatment. Patient satisfaction with MMT was assessed with the VSSS-MT (Pérez de los Cobos et al., 2002) that is a self-reported 27-item scale comprising four factors: Basic Interventions, Specific Interventions, Social Worker Skills, and Psychologist Skills. Basic Interventions mainly assesses doctors' and nurses' skills, and the help received in improving social relationships and self-care. Specific Interventions assesses psychosocial interventions. All items have a five-point Likert scale response option (1 = terrible to 5 = excellent). On items referring to professional manner or activities, participants also have the response option of 'not applicable.' VSSS-MT scores are obtained by averaging applicable items. The ranges of clinical significance for the VSSS-MT scores are (Pérez de los Cobos et al., 2004): 1–2 (very dissatisfied), >2–3 (slightly dissatisfied), >3–4 (slightly satisfied), and >4–5 (very satisfied). In the present study, the VSSS-MT four factors showed acceptable to excellent internal reliabilities (Cronbach's α: 0.93, 0.91, 0.77, and 0.77, respectively).

2.2.2. Perceived participation in methadone maintenance treatment. Following Pérez de los Cobos et al. (2005), patients' participation in treatment decisions was explored by means of two questions. The frequency of information regarding changes in methadone dose was assessed with the following question: 'Are you informed about the changes your centre's staff makes with regard to your methadone dose?' Response options were: 1, never; 2, very rarely; 3, sometimes; 4, almost always; 5, always. Perceived influence on methadone dose changes was ascertained with the question: 'Do you think that your opinion influences your centre's staff to modify the methadone dose you take?' The five-point Likert scale response option to this question was: 1, no; 2, a little; 3, somewhat; 4, quite a lot; 5, a great deal.

2.2.3. Satisfaction with methadone as a medication. The opinion of patients regarding methadone as a medication for treating heroin dependence was explored with the following question (Pérez de los Cobos et al., 2005): 'Taking into account your overall experience, what is your impression about methadone as a medication for carrying out maintenance treatment of heroin dependence?' Response options were: 1, terrible; 2, mostly dissatisfied; 3, neither dissatisfied nor satisfied; 4, mostly satisfied; 5, excellent.

2.2.4. Desired adjustment of methadone dose. The adjustment of methadone dose desired by patients was assessed by means of a vertical visual analogue scale of methadone dose (VAS-MD; Pérez de los Cobos et al., 2005). Instructions to participants were as follows: 'Please indicate with a horizontal mark on the continuous line to what extent you would like to increase (+) or to reduce (−) the daily methadone dose you take currently. If you would prefer to not modify your dose, makes a mark at the level of "same dose" (=).' The mark at this midpoint level was scored as a 0. A VAS-MD score of 0 was considered to indicate an optimal dose adjustment from the patient's perspective. Marks made above or below the midpoint were scored >0–10 and positively or negatively, depending on whether they were made on the top or bottom segment of the scale.

2.2.5. Psychological adjustment. The GHQ-28 (Goldberg and Hillier, 1979; Lobo et al., 1986) is a 28-item self-reported instrument designed for the detection and measurement of current non-psychotic psychopathology. The four seven-item subscales of the GHQ-28 include the Somatic Symptoms subscale, the Anxiety and Insomnia subscale, the Social Dysfunction subscale and the Severe Depression subscale. All items are rated on a four-point scale ranging from a 'better/healthier than normal' option – through a 'no more than usual' and a 'worse/rather more than usual' – to a 'much worse/much more than usual' option (the exact wording for each response option depends upon the specific item content). Higher total and subscale scores indicate greater psychological symptomatology. The traditional GHQ scoring method (0, 0, 1, 1) was used to obtain a continuous measure of psychological adjustment or symptomatology for each of the four GHQ-28 subscales. In the present study, the GHQ-28 four factors showed good to excellent internal reliabilities (Cronbach's α: 0.84, 0.88, 0.81, and 0.90, respectively).

2.3. Procedure

All participants provided written informed consent to take part in the study, which was approved by the Clinical Research Ethics Committee of La Rioja (Logroño, Spain). A research assistant invited randomly selected patients to participate in the study and guided participants through instructions for all instruments, answered their questions regarding scales completion, and stayed during the assessment session until all items were filled out, while ensuring patients' confidentiality. All instruments were administered individually in a single session and without the presence of clinical staff. A compensation of 10 euros was paid for participating in this study that was carried out between January and March 2007.

2.4. Data analyses

In order to identify independent predictor variables of non-participation in the survey, a stepwise logistic regression analysis was performed. Descriptive statistics were used to characterize the study sample. Wherever appropriate, χ^2-tests and unpaired Student's t-tests were conducted to test differences between satisfied and dissatisfied patient groups (VSSS-MT total score >3 vs. $\leq$3). A multiple linear regression analysis was performed to identify variables independently associated with VSSS-MT total score. Finally, a multivariate binary logistic analysis was carried out to examine satisfaction with MMT as a binary dependent variable. For both regression analyses, variable selection was done with a forward stepwise procedure with an entry criterion of $p < 0.05$ and a removal criterion of $p > 0.10$. These two regression analyses incorporated only those variables found to be significant at an alpha level of 0.20 (Afifi et al., 2004) in the bivariate analyses of differences between satisfied and dissatisfied patient groups. All tests of significance were two-tailed, and statistical significance was defined as $p < 0.05$ unless otherwise stated. All analyses were performed using the IBM SPSS statistical package, version 18.0 (SPSS, Chicago, IL, USA).

Table 1
Features of methadone maintenance treatment and methadone treatment centres.[a]

Methadone treatment centres (n)	4[b]
Patient distribution	
Primary care or specialist drug treatment setting	91.9%
Community pharmacy setting	8.1%
Number of patients/centre	137.9 (70.9)
Methadone dispensing hours/week	29.8 (9.1)
Methadone treatment	
Visit to the centre/month	7.8 (6.3)
Patients with take-home doses	80.3%
Urinalysis frequency	
Weekly or more	15.8%
Fortnightly but not weekly	31.6%
Monthly but not fortnightly	47.4%
Half-yearly but not yearly	3.5%
No urinalyses	1.8%
Staff goals	
Abstinence of all opioids	23.0%
Rehabilitation	61.5%
Harm reduction	15.6%

[a] Unless otherwise indicated, values represent means (and standard deviations in parentheses).
[b] All of the 10 pharmacies were considered to constitute a single centre.

3. Results

3.1. Acceptance of the survey

Of the 174 surveys originally intended, 20 could not be carried out for the following reasons: medical discharge after completing methadone detoxification ($n=6$); still in MMT but transferred to another region ($n=5$); MMT patients currently imprisoned ($n=4$); drop-out ($n=2$); death ($n=2$); others ($n=1$). Of the 154 MMT patients who were finally invited to participate in the study, 123 (79.9%) accepted. If the participation rate is calculated based on the 174 surveys initially planned, a smaller but equally satisfactory value of 70.1% is obtained.

Those patients who refused to participate in the survey, compared with those who accepted, were younger (35.5 (5.8) vs. 38.8 (7.5) years, $t(145)=2.30$, $p=0.023$) and had stayed shorter on their current MMT episode (26.8 (25.3) vs. 41.1 (43.5) months, $t(83.52)=2.26$, $p=0.027$). The results of a binary logistic regression analysis showed that among these two variables only age was independently associated with an increased probability (Odds Ratio [OR] = 1.063, 95% Confidence Interval [CI]: 1.002–1.129) of participation in the survey (Hosmer and Lemeshow test: $\chi^2(8)=10.544$, $p=0.229$).

3.2. Participant, methadone maintenance treatment and centre features

The study sample included 123 patients, ranging in age from 20 to 61 years, with a mean of 38.8 (SD = 7.5) years. Males accounted for 74.8% of the sample. The average years of education were 10.0 (SD = 3.3). Regarding marital status, 63.6% were single, 24.0% married or living with a stable partner, 9.9% separated or divorced and 2.5% widowed. Participants used or had used heroin intravenously (52.8%), intrapulmonary (44.7%) or intranasally (2.4%). Table 1 shows the features of MMT and of the methadone treatment centres where the surveys were carried out. The mean of patients' total MMT episodes was 1.7 (SD = 0.9, range: 1–4). The methadone dose (mg/d) prescribed by physicians was 64.8 (SD = 33.0, range: 6–230). The proportion of patients who received < 60 mg/d of methadone was 38.5%; those receiving 60–100 mg/d, 54.1%, and >100 mg/d, 7.4%. Patients had been on their present dose for 17.8 (SD = 23.8) months, and in MMT for 41.1 (SD = 43.5) months.

Table 2
Categorical results of the Verona Service Satisfaction Scale for Methadone Treatment (VSSS-MT).[a]

	Dissatisfied		Satisfied	
	Very (%)	Slightly (%)	Slightly (%)	Very (%)
VSSS-MT, total ($n=123$)	4.1	27.6	57.7	10.6
Basic interventions ($n=118$)	5.9	16.1	57.6	20.3
Specific interventions ($n=104$)	16.3	29.8	51.9	1.9
Social worker skills ($n=59$)	10.2	37.3	33.9	18.6
Psychologist skills ($n=43$)	2.3	41.9	37.2	18.6

[a] Categorical results show the distribution of VSSS-MT mean scores for each participant within the following VSSS-MT score ranges: 1–2 (very dissatisfied), >2–3 (slightly dissatisfied), >3–4 (slightly satisfied), and >4–5 (very satisfied). VSSS-MT: Verona Service Satisfaction Scale for Methadone Treatment.

3.3. Satisfaction with methadone maintenance treatment

The mean VSSS-MT total score was 3.4 (SD = 0.6). This result indicates 'slight satisfaction', according to the VSSS-MT score ranges of clinical significance (Pérez de los Cobos et al., 2004). Regarding the different VSSS-MT factors, participants had mean scores of 3.5 (SD = 0.7) for Basic Interventions, 3.1 (SD = 0.8) for Specific Interventions, 3.5 (SD = 1.0) for Social Worker Skills, and 3.6 (SD = 0.9) for Psychologist Skills. Table 2 shows the categorical analysis of the VSSS-MT scores. This analysis was performed by distributing each participant's VSSS-MT mean score over the ranges of this scale's clinical significance. The percentage of patients who felt overall dissatisfied (VSSS-MT total score ≤ 3) and satisfied (VSSS-MT total score > 3) was, respectively, 31.7 and 68.3%.

Dissatisfied patients were significantly younger when they initiated heroin use (18.8 (3.7) vs. 20.8 (6.5) years, $t(115.57)=-2.10$, $p=0.038$), reported more years of education (10.9 (4.1) vs. 9.6 (2.8), $t(118)=2.13$, $p=0.035$), and tended to have been on their current methadone dose for more days (681.4 (915.7) vs. 463.4 (589.3), $t(112)=1.53$, $p=0.128$). Likewise, dissatisfied patients tended to have a greater likelihood of being treated in a centre with a lesser number of both patients (124.1 (75.2) vs. 144.3 (68.4), $t(121)=-1.48$, $p=0.143$) and hours per week that methadone was dispensed (27.9 (11.3) vs. 30.8 (7.8), $t(55.75)=-1.46$, $p=0.150$).

3.4. Perceived participation in methadone maintenance treatment

With regard to changes in methadone dose by physicians, 73.8% of patients referred a perceived high frequency of information about these changes, and 54.5% believed that their opinions influenced these changes 'a great deal' or 'quite a lot.' These groups of patients overlapped notably, since up to 42.3% scored highly in both questions. Patients dissatisfied with MMT, compared to satisfied patients, reported less frequency in being informed about changes in methadone dose (3.5 (1.7) vs. 4.2 (1.4), $t(63.98)=-2.37$, $p=0.020$) and as having significantly less influence on methadone dosage regulation (2.9 (1.3) vs. 3.5 (1.4), $t(121)=-2.33$, $p=0.022$).

3.5. Satisfaction with methadone as a medication

Although most participants had an excellent (33.3%) or mostly satisfied (35.0%) opinion of methadone as a medication for treating opioid dependence, almost a third of the participants expressed an opinion that was neither dissatisfied nor satisfied (19.5%), mostly dissatisfied (2.4%) or terrible (9.8%). There was no statistically significant difference between the dissatisfied and the satisfied with MMT groups regarding the opinion of methadone as a medication (3.6 (1.3) vs. 3.9 (1.2), $t(121)=-0.97$, $p=0.335$).

Table 3
Multiple linear regression model of factors independently associated with satisfaction with methadone maintenance treatment (VSSS-MT total score).[a]

Variables[b]	*B*	SE	*p*-Value	*β*
Number of hours per week that the centre dispensed methadone	0.013	0.007	0.055	0.193
Perceived influence on methadone dose changes	0.089	0.041	0.031	0.194
Perceived frequency of receiving information about methadone dose changes	0.107	0.038	0.006	0.246
Number of patients per centre	0.002	0.001	0.023	0.233
Social Dysfunction subscale (GHQ-28)	−0.053	0.026	0.042	−0.179

[a] VSSS-MT: Verona Service Satisfaction Scale for Methadone Treatment.
[b] Variables entered into the analysis but found not to be statistically significant were Age at first heroin use, Time on current methadone dose and Number of years of education completed.

3.6. *Desired adjustment of methadone dose*

The mean score of VAS-MD was −2.5 (SD = 3.5). The difference between this mean and the VAS-MD score of 0, the value indicating an optimal adjustment of methadone dose, was statistically significant (mean difference = −2.5, 95% CI −3.1 to −1.8, $t(121) = -7.81$, $p < 0.001$). This result indicates that most patients would have preferred a downward adjustment in methadone dose. A categorical analysis of VAS-MD showed that 41.8% of participants preferred not to modify their dose (VAS-MD score = 0), whereas 54.1% preferred to reduce it (VAS-MD score < 0), and 4.1% wanted to raise it (VAS-MD score > 0). Patients who were dissatisfied with their MMT, compared to satisfied patients, scored similarly on the VAS-MD (−2.9 (4.1) vs. −2.3 (3.2), $t(58.25) = -0.84$, $p = 0.405$).

3.7. *Psychological adjustment*

The mean GHQ-28 total score for the entire sample was 8.2 (SD = 7.1). GHQ-28 subscales' mean scores were 2.3 (SD = 2.3) for Somatic Symptoms, 2.7 (SD = 2.3) for Anxiety and Insomnia, 1.8 (SD = 2.2) for Social Dysfunction, and 1.5 (SD = 2.2) for Severe Depression. Patients dissatisfied with MMT, compared to satisfied patients, had significantly higher scores on the Social Dysfunction subscale (2.4 (2.5) vs. 1.5 (1.9), $t(58.7) = 2.13$, $p = 0.037$). There were no other statistically significant differences on the remaining GHQ-28 subscales.

3.8. *Determinants of satisfaction with methadone maintenance treatment*

As shown in Table 3, linear multiple regression analysis (whole model $F(5,104) = 7.311$, $p < 0.0001$, $R^2 = 0.260$) revealed that variables independently associated with VSSS-MT total score were number of hours per week that the centre dispensed methadone, perceived influence on methadone dose changes, perceived frequency of receiving information about methadone dose changes, number of patients per centre and Social Dysfunction subscale of GHQ-28 (lower Social Dysfunction was related to higher satisfaction).

In a quite similar way, the multivariate binary logistic regression results (Table 4) shows that the following four variables were significantly and independently associated with the likelihood of being satisfied with MMT (Hosmer and Lemeshow test: $\chi^2(8) = 2.645$, $p = 0.955$; Nagelkerke's $R^2 = 0.253$): number of years of education completed (high levels of education related to less satisfaction), number of patients per centre, perceived frequency of receiving information about methadone dose changes, and Social Dysfunction subscale of GHQ-28 (again, lower Social Dysfunction was related to higher satisfaction). However, number of hours per week that the centre dispensed methadone and perceived influence on methadone dose changes were not significantly associated with satisfaction with MMT in this analysis as they were in the linear regression model.

4. Discussion

As far as we are aware, this study represents the first attempt to assess both mental health status and satisfaction with treatment in MMT patients, as well as the first in which patient satisfaction with MMT has been evaluated in a representative sample of MMT patients of an entire region. Study participants, as a whole, reported slight satisfaction with MMT, with approximately 32% of them feeling dissatisfied. Similar scores of satisfaction have been found in two previous surveys, one carried out across in Spain (Pérez de los Cobos et al., 2004) and another within the Valencia Region (Pérez de los Cobos et al., 2005). However, the percentage of dissatisfied patients was almost twice the obtained in the aforementioned studies. This marked difference could stem from the fact that patients from La Rioja might expect higher quality of services, given the high-quality level of most services available to the residents of one of the Spanish regions with a higher per capita income in Spain. Moreover, the categorical analysis of the VSSS-MT scores revealed clearly that as a whole and with basic interventions, many more patients were satisfied than dissatisfied. Percentages of satisfied and dissatisfied patients were more balanced with regard to the remaining VSSS-MT subscales, suggesting thus that specific interventions and social worker or psychologist skills tend to cause more divergent patient opinions than basic interventions.

Among the broad set of variables – relating to the patient, his/her perspective about some MMT-related issues, the MMT itself, and the methadone treatment centre – assessed through the present study, the following variables have been identified as independently associated with VSSS-MT total score and/or the likelihood of

Table 4
Binary logistic regression model of factors independently associated with the likelihood of being satisfied with methadone maintenance treatment (VSSS-MT total score > 3).[a]

Variables[b]	*B*	Wald χ^2	*p*-Value	OR	95% CI
Number of years of education completed	−0.181	6.138	0.013	0.835	0.723–0.963
Number of patients per centre	0.009	6.564	0.010	1.009	1.002–1.015
Social Dysfunction subscale (GHQ-28)	−0.291	7.312	0.007	0.748	0.605–0.923
Perceived frequency of receiving information about methadone dose changes	0.452	8.098	0.004	1.571	1.151–2.145

[a] VSSS-MT: Verona Service Satisfaction Scale for Methadone Treatment.
[b] Variables entered into the analysis but found not to be statistically significant were Age at first heroin use, Time on current methadone dose, Number of hours per week that the centre dispensed methadone and perceived influence on methadone dose changes.

being satisfied with MMT: number of hours per week that the centre dispensed methadone, number of patients per centre, number of years of education completed, perceived influence on methadone dose changes, perceived frequency of receiving information about methadone dose changes, and Social Dysfunction subscale of GHQ-28. Both the opening hours of methadone treatment centres and the patient's perception of being informed about methadone dose changes have already been independently and positively associated with patient satisfaction in the national Spanish survey (Pérez de los Cobos et al., 2004) and in the study performed in the Valencia Region (Pérez de los Cobos et al., 2005), respectively. Likewise, the fact that higher levels of education were related to being more dissatisfied with treatment is a fairly common finding in previous research on patient satisfaction in diverse populations and health care settings (see Crow et al., 2002, for a review). As to the opening hours of methadone treatment centres, a manifest indicator of the methadone treatment centre's accessibility, a previous study performed in Australia had noted that is, by far, the variable that opioid-dependent patients would most like to change (Ward, 2000). Regarding the patient's perceptions of being informed about and influencing on methadone dose changes, two variables operationalizing different levels of the same construct (i.e., perceived participation in MMT), their significant and positive effect on overall satisfaction levels is consistent with previous findings of a positive association between patients' participation in and satisfaction with treatment (Brener et al., 2009; Fischer et al., 2007).

The positive and significant relationship found between the number of patients per centre and satisfaction with MMT should be interpreted taking into account both the particular upper limit of the number of patients per methadone treatment centre (i.e., 197) and the reduced number of patients at community pharmacies dispensing methadone. Therefore, the number of patients per centre can hardly be considered as an overcrowding indicator but as a surrogate variable of centre's experience and/or availability of services. The positive association found may be thus interpreted in this latter sense.

Deterioration in social functioning (Social Dysfunction subscale of GHQ-28) was the only clinical variable found to be significantly associated with the VSSS-MT total score (patients with higher scores on Social Dysfunction were more prone to express lower levels of satisfaction with MMT). This inverse association is consistent with the results of a previous study conducted in community mental health centres (Ruggeri et al., 2007). A possible explanation for this inverse relationship could lie in the fact that MMT patients with a higher deterioration in social functioning may consider that one of their core needs has been insufficiently met by current MMT. This patient subgroup would probably benefit from more careful assessment and attention to the social problems that they must face. One may speculate that other models of MMT, such as recovery-oriented methadone maintenance (White and Mojer-Torres, 2010), may lead to improve the levels of social functioning of these patients and, thus, increase their satisfaction with treatment.

In light of the results, it is worth mentioning the robustness of some of the findings (i.e., satisfaction related to number of patients per centre, perceived frequency of receiving information about methadone dose changes and Social Dysfunction subscale of GHQ-28), since they were obtained by means of two complementary multivariate analyses.

The present study, however, has some limitations. Firstly, patients who had been treated in prisons, who dropped out of MMT or who had stayed less than 3 months in MMT were not surveyed. Secondly, there was a fairly high rate of refusal to participate in the study. Notwithstanding the number of non-participants, accuracy provided by the original targeted sample size (5%) and the actual sample size (6.6%) was comparable. Thirdly, despite being a reference instrument for psychopathological screening in both the general population and non-psychiatric settings, the GHQ-28 may suffer from some limitations when used for assessing mental health status in a group of patients with a usually high prevalence of psychiatric comorbidity. One of these limitations would be that GHQ-28 only assesses non-psychotic psychopathology, but in any case psychotic disorders are not frequent in opioid-dependent patients (Rounsaville et al., 1982) and an antipsychotic effect of methadone has been postulated (Brizer et al., 1985; Gold et al., 1977). In spite of these limitations, the GHQ-28 has been widely used in patients with opioid dependence (e.g., Darke et al., 1992, 1994; González-Sáiz et al., 1998, 2009; Hartgers et al., 1992; Swift et al., 1990) and was selected in order to seek the best possible balance between the brevity of the whole survey and the validity of the assessment. Fourthly, a large number of bivariate analyses have been conducted, with the consequent risk of inflating the probability of type I errors. In order to limit this problem, the discussion focuses on the results of the multivariate analyses. Fifthly, due to the exploratory nature of the analyses carried out in the present study, the predictive validity of the models derived from both multivariate regression analyses need to be confirmed in other data sets. Sixthly, the cross-sectional design employed, although a common problem in most patient satisfaction studies, limits the interpretability scope of some of the associations found between satisfaction with MMT and patients' variables. Finally, the findings of the present study may not be generalizable to other methadone-maintained populations from Spain or other geographical areas, given the potential, unknown differences arising from both patient variables and MMT programmes or centres managed differently than in the Region of La Rioja. Nonetheless, the generalizability of the results to other settings sharing a similar model of MMT is likely to be quite good.

Despite these study limitations, the results obtained show that the variables explored in the present study accounted for a considerably larger proportion of the variance in satisfaction with MMT (26% and 25.3% for linear- and logistic-regression models, respectively) than the percentage explained in other studies (Pérez de los Cobos et al., 2004, 2005, 2007) performed with the same instrument (i.e., the VSSS-MT), in near geographical areas, but taking into account other or only some of the variables considered in the present study. This fact deserves to be emphasized because of its relevance for any process of continuous quality improvement of MMT. Obviously, the higher the explained variance of satisfaction with treatment, the greater the ability to identify potential successful interventions to ultimately improve satisfaction with MMT. Further research is thus needed both to confirm these results in different populations of MMT patients and to investigate the role of factors other than the many explored in the present study (e.g., patient expectations and needs, centre policies, patient's and provider's beliefs and attitudes about the goal of MMT) in predicting satisfaction with MMT.

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Contributors

Joan Trujols, José Pérez de los Cobos and Juan del Pozo designed the study and wrote the protocol. Joan Trujols and Núria Siñol managed the literature searches and summaries of previous related work. Data collection was done by Inmaculada Garijo. Joan Trujols and José Pérez de los Cobos designed the analysis plan. Joan Trujols undertook the statistical analysis. All authors participated in the interpretation of the findings. Joan Trujols wrote the first draft of the manuscript. All authors contributed to and have approved the final manuscript.

Conflict of interest

As Head of the Drug Addiction Service (General Directorate of Public Health and Consumer Affairs, Regional Ministry of Health, Government of La Rioja), Juan del Pozo is an employee of the Government of La Rioja, administration that commissioned and funded partially the study. The rest of authors declare no financial interests or potential conflicts of interest related directly or indirectly to this study.

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Trujols, J., Portella, M.J., Iraurgi, I., Campins, M.J., Siñol, N. i Pérez de los Cobos, J. (2013). Patient-reported outcome measures: are they patient-generated, patient-centred or patient-valued? *Journal of Mental Health*, *22*, 555-562.

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REVIEW

Patient-reported outcome measures: Are they patient-generated, patient-centred or patient-valued?

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Abstract

Background. In the past two decades, there has been a growing interest in the development of a more patient-centred approach to assessing treatment outcomes. This interest has resulted in the increasing use of patient-reported outcome measures (PROMs) in both clinical trials and usual clinical practice.

Aims. To briefly discuss the paucity of efficacy and effectiveness studies in the field of mental health (exemplified by schizophrenia, depression and opioid dependence) that significantly incorporate the patient's perspective. The limited concordance between the perspectives of patients and clinicians in outcome assessment is also addressed. Finally, we propose a new PROM classification system based on the degree to which these instruments incorporate the patient's perspective.

Conclusions. PROMs may differ little from traditional instruments unless they truly incorporate the patient's perspective and not just the perspectives of clinicians and researchers. Efforts to develop new PROMs that provide a more patient-centred outcome assessment should use qualitative and participatory methods to capture and incorporate patient perspectives and values.

Keywords: *mental health outcome measures, patient-centred outcome assessment, patient-reported outcome measures, patient's perspective, service user involvement, measurement, outcome studies*

Introduction

One of the biggest challenges facing mental health service providers and researchers is selecting the appropriate outcome variables to assess treatment and services. As Tugwell and Boers (1993) noted about the outcome measures used in rheumatoid arthritis clinical trials, the results of any study are only as reliable as the outcome variables chosen. This assertion is true for clinical trials, but is also valid for "real-world" studies of effectiveness. The results of both types of studies are strongly influenced by the selection of outcome variables. This observation is particularly relevant considering that many outcome measures used in clinical

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trials are of limited use in assessing treatment results under the conditions of everyday clinical practice (Hunter et al., 2009), and that service users' and clinicians' views of what is a desirable or successful outcome can differ greatly (Perkins, 2001).

In the past two decades, there has been a growing interest in the development of a more patient-centred approach to assessing treatment outcomes. This interest has resulted in the increasing use of patient-reported outcome measures (PROMs) in clinical trials (Doward et al., 2010) and usual clinical practice (Greenhalgh et al., 2008). However, it is worth pointing out that PROMs can be similar to traditional instruments unless they truly incorporate the patient's perspective and not just the perspectives of clinicians and researchers. PROMs developed in a conventional manner are unlikely to assess the aspects that matter most to patients. Research that is based on truly patient-centred outcomes requires not just self-reported instruments, but rather instruments that have been developed with direct input from patients. To gain a genuine understanding of the patients' perspective we must utilise more collaborative forms of patient participation (Staniszewska et al., 2012), perhaps even user-led research (Rose et al., 2011), in order to develop PROMs.

In this article, we discuss the paucity of efficacy and effectiveness studies in the field of mental health that incorporate, in any relevant way, the patient's perspective into outcome assessment. Examples are provided from three different disorders: schizophrenia, depression and opioid dependence. In addition, we propose a new PROM classification system based on the degree that these instruments incorporate the patient's perspective.

The patient's perspective in the evaluation of treatment outcomes in schizophrenia

Despite the current debate surrounding the most appropriate outcome variables to assess the efficacy and effectiveness of treatments for schizophrenia, patient preferences have barely been considered (Kinter et al., 2009). As early as 1990s, Collins et al. (1991) criticised the over-emphasis placed on symptom suppression as the sole outcome variable. According to those authors, the effectiveness of such treatments may be partially distorted if patient functioning, quality of life, and wellbeing were not considered as outcome variables. Current clinical trials of anti-psychotic drugs face a variety of methodological problems, including – as Leucht et al. (2008) have noted – a lack of hard endpoints, the use of difficult-to-interpret assessment scales, and an absence of uniform definitions of response and remission. In order to remedy these problems, Kane and Leucht (2008) have suggested placing a greater emphasis on the patient's experience and point-of-view. Many patient concerns are not addressed in clinical research, and patients and clinicians should jointly identify common priorities that can be assessed in clinical trials (Partridge & Scadding, 2004). This call to involve patients in selecting outcome variables and designing outcome measures is not new: more than a decade ago Thornley and Adams (1998) called for clinical trials in which the outcome assessment included both patient and clinician perspectives. For patients, relevant aspects are often related to improvement or recovery, and in deciding how to evaluate this (Lloyd et al., 2006). Far too often, clinical trials do not appropriately reflect patients' values or priorities but instead concentrate on outcome variables defined by the scientific and clinical community (Bridges & Jones, 2007).

This failure to incorporate the patient's perspective is particularly evident in most scales used in clinical trials. The responsibility of designing, developing, and administering these instruments, falls upon the clinicians and researchers, with little input from patients. As Rosenheck et al. (2005) found, most scales and instruments used to measure treatment outcomes in schizophrenia (e.g. positive and negative symptomatology, side-effects, quality of life) were developed by the researchers alone. Apart from having adequate psychometric properties, measurement instruments should evaluate aspects that are relevant to the individuals who will answer them – and to do so requires patient involvement in the instrument development process. Outcome measures developed without patient input may be irrelevant, and this situation threatens both the content validity and basic bioethical principles (Hagell et al., 2009). Although few in number, several PROMs explicitly and purposely developed with patient input do exist (Bridges et al., 2010; Martin et al., 2005; Wilkinson et al., 2000). In fact, some have even been entirely developed by patients (Greenwood et al., 2010; Rose et al., 2008, 2009). Unfortunately, however, these PROMs are rarely used nowadays in clinical trials or even in clinical practice.

The remission construct in depressive disorders and its assessment from a patient-based perspective

The state of outcomes assessment in depressive disorders is similar to that described above for schizophrenia. That is to say, because mainstream research does not consider patient input to be important, the patient's perspective has largely been disregarded when designing assessment tools. However, a notable exception is the research work carried out by Zimmerman et al. (2006a, 2011). According to these authors, patients tend to consider the presence of positive mental health characteristics (e.g. optimism, vigour, self-confidence) as a better indicator of remission than the mere lack of depressive symptoms (Zimmerman et al., 2006a). Based on these findings, this same group (Zimmerman et al., 2011) designed the self-reported Remission from Depression Questionnaire (RDQ). The RDQ includes numerous aspects that patients consider to be relevant to remission. Thus, the RDQ is not simply another symptom-based scale, but rather a pragmatic scale that assesses levels of positive mental health, satisfaction with life, overall sense of well-being, and social- and work-related functioning, alongside the more traditional depressive symptoms (Zimmerman et al., 2011). This instrument is a promising tool because it includes, as non-interchangeable features, both self-reported severity of symptoms and perceived psychosocial functioning (Zimmerman et al., 2006b). This self-reported scale thus overcomes the limitations of traditional approaches that assess remission based only on symptom alleviation (Romera et al., 2011; Zimmerman et al., 2006b). The RDQ is the first instrument capable of assessing remission in depressive disorders from a patient's perspective.

Methadone maintenance treatment (MMT) for opioid dependence: outcome assessment from a patient-based perspective

Evaluation of opioid dependence treatment, especially methadone maintenance treatment (MMT), is also a good example of what is known as the "paradox of desynchrony" (Bilsbury & Richman, 2002), a phenomenon that refers to the limited or complete lack of correlation between the different perspectives in outcome assessment.

Trujols et al. (2011) compared patient assessment of MMT outcomes to clinician (i.e. psychiatrist and nurse) reported outcomes in order to assess agreement between the two. Two parallel versions of the same instrument were used (i.e. the Patient Global Impression of Improvement scale and the Clinical Global Impression for Improvement scale). The authors found a large divergence (i.e. lack of concordance) between patient-reported and nurse/psychiatrist reported improvement. This discrepancy has also been reported by Pulford et al. (2009), who performed a similar study in patients treated for substance use dependence, and by De Maeyer et al. (2009), who explored the construct of quality of life as perceived by patients treated for opioid dependence. De Maeyer and colleagues found that patients spontaneously referred to many more aspects (e.g. "interpersonal relationships", "social inclusion" and "self-determination" dimensions) than those typically included in health-related quality of life instruments. Importantly, the authors emphasised the need to develop patient-centred PROMs to perform an assessment of quality of life that truly reflects patient perspectives.

In light of the above findings, it is imperative that we discard the implicit and naive assumption that MMT patients and treatment providers interpret the constructs of quality of life and improvement in the same way. Indeed, a non-negligible number of authors (Balian & Altenberg, 2009; Koester et al., 1999; Trujols & Pérez de los Cobos, 2005) have stressed the need to consider patient priorities in (a) rethinking what is meant by a successful MMT or any other type of intervention and/or (b) establishing the outcome dimensions and variables that should be assessed to establish the effectiveness of such interventions. That said, we should note that several evaluation models and PROMs that incorporate the patient's perspective – to a greater or lesser degree – have already been developed (Lee & Zerai, 2010; Lozano Rojas et al., 2008; Ruefli & Rogers, 2004).

PROMs: whose perspective?

PROM is an umbrella term used to describe any self-report instrument aimed at assessing how patients perceive, feel and interpret their health status and treatment. PROMs commonly evaluate domains such as symptom experiences, functional status, health-related quality of life, wellbeing, and satisfaction with care services or with a given treatment. However, "patient-reported" only implies that the instrument – generally a questionnaire – is completed by the patient. Emphasis is therefore placed on the source of the information (i.e. the patients), rather than on its content. Indeed, as Doward and McKenna (2004) suggested, we should not infer that "patient-reported" means that the information so obtained actually reflects patient concerns.

If we truly wish to respect and reflect patient priorities and perspectives, then we must evaluate PROMs to determine the extent to which they include the patient perspective. Our efforts to classify PROMs in this way are described below. We propose a classification system that divides PROMs into four distinct categories, as follows.

(i) A *patient-generated and patient-reported outcome measure* (PG-PROM) is a PROM specifically developed from the perspective of users of mental health services. Development of this type of PROM is based on a mixed methods approach in which qualitative and participatory research techniques are used to identify potential outcome domains and variables for item and scale construction, and then the resulting instrument is evaluated by the usual psychometric methods to estimate its measurement properties (Rose et al., 2011). The resulting PROM, which will contain both Likert items and open-ended questions, is thus also considered a mixed-methods data collection approach (Rose et al., 2011). The main defining characteristic of the PG-PROM is that all those involved in the different phases of its development are (or have been) recipients of the treatment or service to be evaluated (Rose et al., 2011). To the best of our knowledge, most of the PG-PROMs currently available (Evans et al., 2012; Greenwood et al., 2010; Rose et al., 2008, 2009) have been developed by the Service User Research Enterprise at the Institute of Psychiatry in London, a research group that has designed and standardized the model for developing this type of PROM (Rose et al., 2011).

(ii) A *patient-centred and patient-reported outcome measure* (PC-PROM) is a PROM that is explicitly developed – to a greater or lesser extent – with the participation of mental health service users. A well-known example is the Carers' and Users' Expectation of Service-

User Version (CUES-U; Lelliott et al., 2001). Thus, even though other stakeholders (e. g. clinicians, researchers, family members, and/or administrators) have participated in developing the instrument, the patients themselves have made major contributions. In most cases, patient participation occurs during the initial stages of identifying the dimensions, variables, and/or indicators to be assessed; in addition, patients are also likely to participate in drafting and evaluating the initial or pilot version of the instrument. This type of PROM is also developed using a mixed methods approach: the methodology used to initially develop the instrument is characteristically qualitative (mainly focus groups and/or in-depth interviews), whereas the subsequent study of its psychometric properties is essentially quantitative. Qualitative research allows for a direct and in-depth understanding of patient perspectives on their condition, their health status, and treatment thereof. The qualitative component of constructing a PC-PROM is essential to genuinely incorporate patient input (Lasch et al., 2010). This type of PROM can be more or less patient-centred depending on the vigour with which this critical qualitative research component is conducted.

(iii) A *patient-valued and patient-reported outcome measure* (PV-PROM) is a PROM that most patients value (Kabir & Wykes, 2010) because it reflects – at least to some extent – their perspectives. In other words, patients perceive that the instrument has been designed by someone who understands the patients' situation and that the PROM measures factors that are of importance to them (Kabir & Wykes, 2010). The difference between the two types of PROM described above (PG- and PC-PROMs) and a PV-PROM is that PV-PROMs are developed without direct patient participation. To determine whether a PROM developed without patient participation can be considered patient-valued, qualitative research methods – focus groups, in-depth interviews, or cognitive interviews – must be adopted (Paterson, 2004). Instruments developed without patient participation cannot be classified as a PV-PROM until they have been evaluated and determined to be patient-valued by one or more of the methods described above.

(iv) A *patient-irrelevant and patient-reported outcome measure* (PI-PROM) is a PROM that has been (a) developed without any patient participation and (b) assessed by patients as irrelevant or of no interest or value. This type of PROM tends to focus on aspects considered relevant by clinicians or researchers but not by patients themselves. Thus, most questions and topics considered important by the patients are not included in such instruments, while the aspects that are included are largely considered irrelevant by mental health service users. As such instruments do not assess those domains and variables that are relevant to patients, the instrument is unlikely to be valid and will probably be relatively unresponsive to change, and difficult to interpret (Carr & Higginson, 2001). Likewise, this type of PROM usually yields a higher non-response rate, more missing data, and also generates numerous clarifying queries from patients (Doward et al., 2010). Such PROMS also increase the likelihood of patients interpreting items in a manner inconsistent with the instrument's conceptual framework. Finally, this type of PROM may alienate patients by making them feel that their views are not fully appreciated or valued (Doward et al., 2010).

Corollary

To develop a new PROM, the degree to which the instrument incorporates the patient's perspective, which we have now divided into four distinct categories of PROMs, must be taken into account. If the aim of the instrument is to provide a patient-centred outcome assessment, then the most patient-centred instruments (i.e. PC- and PG-PROMs) should be used. Researchers who wish to use off-the-shelf PROMs – most of which have been developed largely without direct patient participation – should first evaluate these to determine how patient-centred they are in order to select the most appropriate PROM for patient-centred assessment. Fortunately, some researchers have already begun to investigate users' views on the relevance and acceptability of commonly used outcome measures (Crawford et al., 2011).

Likewise, the weak concordance and significant differences between traditional and patient-centred outcome assessment should not be considered as undesirable but rather the exact opposite; such differences are an extraordinary source of information for the development and provision of individualised treatments adapted to patients' various needs.

The extra effort required to develop PROMs that patients consider relevant (i.e. PG-, PC- and PV-PROMs) and that are also psychometrically robust, should not be an obstacle. PROMs that are irrelevant to patients – even if psychometrically robust – do not ensure a genuinely patient-centred outcome assessment. As Bilsbury and Richman (2002, p. 10) noted, "a quest for statistical psychometric virtue is futile if the instrument is so ill-focused that it is irrelevant to the individual".

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ORIGINAL RESEARCH

A critical analysis of user satisfaction surveys in addiction services: opioid maintenance treatment as a representative case study

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Background: Satisfaction with services represents a key component of the user's perspective, and user satisfaction surveys are the most commonly used approach to evaluate the aforementioned perspective. The aim of this discursive paper is to provide a critical overview of user satisfaction surveys in addiction treatment and harm reduction services, with a particular focus on opioid maintenance treatment as a representative case.

Methods: We carried out a selective critical review and analysis of the literature on user satisfaction surveys in addiction treatment and harm reduction services.

Results: Most studies that have reported results of satisfaction surveys have found that the great majority of users (virtually all, in many cases) are highly satisfied with the services received. However, when these results are compared to the findings of studies that use different methodologies to explore the patient's perspective, the results are not as consistent as might be expected. It is not uncommon to find that "highly satisfied" patients report significant problems when mixed-methods studies are conducted. To understand this apparent contradiction, we explored two distinct (though not mutually exclusive) lines of reasoning, one of which concerns conceptual aspects and the other, methodological questions.

Conclusion: User satisfaction surveys, as currently designed and carried out in addiction treatment and harm reduction services, do not significantly help to improve service quality. Therefore, most of the enthusiasm and naiveté with which satisfaction surveys are currently performed and interpreted – and rarely acted on in the case of nonoptimal results – should be avoided. A truly participatory approach to program evaluation is urgently needed to reshape and transform patient satisfaction surveys.

Keywords: patient satisfaction, substance abuse treatment services, harm reduction services, patient-centered evaluation, service user perspective, user involvement

Introduction

Interventions and programs addressing drug use and related harms have traditionally been evaluated primarily by "hard" indicators or criteria,[1] including program retention rates, use of the primary drug of abuse and other psychoactive substances, morbidity/mortality, and criminal activity, among others. These criteria are relevant and necessary to inform health care policies; however, they do not necessarily reflect the priorities of those who use harm reduction or addiction treatment services.[2,3] Moreover, there is evidence showing that user perspectives do not correlate with staff perspectives,[4,5] a well-described phenomenon known as the "paradox of desynchrony."[6] Therefore, it is clear that a more inclusive and comprehensive evaluation of the process and outcomes of interventions should include users' assessment of these variables.[1]

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Satisfaction surveys, a key component of assessing the service user's perspective,[7] have long been the most commonly used method of exploring this perspective.[8] User satisfaction surveys assessing addiction treatment and harm reduction services have consistently found high skewness toward positive satisfaction scores.[9–12] While this could be interpreted with great enthusiasm, other hypotheses should be considered, such as publication bias, lack of clarity of norms against which to compare the treatments, the psychometric properties of the instruments used, and the lack of an underlying theoretical framework of patient satisfaction.[13,14] The aim of this paper is to provide a critical overview of user satisfaction surveys as currently carried out in addiction treatment and harm reduction services, with a special focus on opioid maintenance treatment (OMT) as a representative case. First, we argue the lack, relevance, and need for a more patient-centered approach to program evaluation. Then, we analyze the main features of client satisfaction surveys conducted at OMT centers as well as conceptual and methodological issues that may explain why the results of such surveys often diverge from results obtained via other data collection/generation methods. Finally, based on the discussion of some limitations of patient satisfaction surveys as currently performed, we suggest alternative directions for inquiry and research focused on a truly user-participatory approach to program evaluation.

Towards a more user-centered approach to program evaluation

When conducting a user-centered evaluation of OMT services, several indicators or assessment areas should be considered: a) user expectations and objectives for the treatment or intervention,[15,16] b) patient beliefs or opinions about medication (primarily methadone or buprenorphine),[17–21] c) user appraisal of the relational dynamic with intervention providers[22–24] and the degree of perceived participation in decision-making,[25,26] as well as patient preferences for a participatory or deferential role,[27,28] d) indicators of user-perceived quality,[29] e) client perception of unmet needs,[30,31] and f) level of satisfaction with treatment.[8,11,25,32]

Despite the relevance and validity of the aforementioned factors in facilitating adherence to the intervention[10,33–35] and in measuring service quality,[36,37] very few programs or centers evaluate these factors on a routine basis. This is surprising given that program adherence and service quality are two areas in which the importance of these variables is readily apparent. On one hand, these variables influence program acceptability and given that acceptability can affect adherence, these variables may mediate – at least partially – the efficacy of the interventions. On the other hand, the accreditation process of some types of treatment centers (eg, methadone treatment centers) requires the periodic evaluation of certain variables (generally, patient satisfaction) to assess quality.[38,39]

These variables (or more generally speaking, the user's perspective) have generally received scant attention[40,41] and have been largely ignored by the community of mainstream researchers,[42] who do not acknowledge the relevance of such variables in designing, providing, and/or evaluating addiction treatment and harm reduction services. This lack of research on user perspectives contrasts with the many studies evaluating interventions and treatments. This is particularly worrisome considering that input from service users is essential if we are to define, implement, and evaluate these interventions and programs, ensuring they meet the needs of the users themselves.[43] Needless to say, a more in-depth understanding of user perspectives of interventions and centers would allow us to better interpret the efficacy and quality of interventions, as well as to plan and implement measures to improve those parameters. Without this knowledge, the risk of underestimating or distorting the value of treatment services to users through the usual assessment practices is high.[44]

In recent years, interest in including users' perspectives to evaluate interventions that address substance use appears to be growing. This interest has resulted in the increasing use of patient-reported outcome measures in both clinical trials and usual clinical practice.[45–47] This emerging framework could be related to the current trend toward altering the traditional hierarchical relationship between health care professionals and patients, ie, a relationship based on the classical model of medical practice, which implies a biased and exclusionary perception of drug users as noncompetent persons.[48,49]

Satisfaction surveys, as stated above, are a key component of assessing the service user's perspective[7] and are the most common and most studied approach to exploring the aforementioned perspective.[8] Nevertheless, it is important to keep in mind that most classification systems of the opportunities or levels of participation in addiction treatment and harm reduction services consider user satisfaction surveys to be "low-involvement" activities (Table 1).[50–52] In fact, some authors prefer to exclude user satisfaction surveys from the definition of participation because such surveys do not entail the existence of mechanisms to modify planning processes in response to the survey's findings, nor do they imply that service users participate as equal interlocutors.[53]

Table 1 Levels of user-participation or opportunities for user-participation in addiction treatment and harm reduction services

Degree of user involvement	Type of participation	Example of activity
High	Activities implying a share in decision-making	User's representatives involved in service planning committees
		User's representatives attending staff meetings
		User's representatives involved in staff recruitment
		User's representatives involved in staff performance appraisal
Mild	Activities in which service users have nondecision-making roles	Users involved in writing or reviewing informative fact sheets or educational materials
		Users involved in staff training
	Activities promoting and supporting user involvement	Availability of an adequate space and schedule within the service to run users own support groups
		Availability of publications or information about the activities of drug user organizations
Low	Activities related to providing information to or receiving information from service users	User councils
		User forums
		User satisfaction surveys
		Suggestion box
		Complaint process
		Adequate display of information concerning changes on policies or service hours
	User-participation built into the values and policies of the service	Charter of rights

Notes: These levels represent a range of opportunities for user-participation. In practice, and due to very diverse reasons (eg, availability of the activity by the service or user's awareness and motivation), participation does not occur in all of these areas, in all services, or in the case of all users. Adapted with permission from Bryant J, Saxton M, Madden A, Bath N, Robinson S. Consumer participation in the planning and delivery of drug treatment services: the current arrangements. *Drug Alcohol Rev.* 2008;27(2):130–137. Copyright © 2009, John Wiley & Sons.[51]

Assessment of client satisfaction in OMT

The number of validated self-reports specifically designed to assess satisfaction with addiction treatment[54,55] and, more specifically, with treatment for opioid dependence,[56,57] are quite limited. Client satisfaction with OMT has been primarily assessed through a) specific questions,[58,59] b) nonvalidated questionnaires designed ad hoc,[60,61] c) nonvalidated adaptations of instruments originally designed to assess satisfaction with mental health services or other types of health care services,[62] or d) validated generic scales designed to assess satisfaction with any type of health care center (ie, not specific to addictions).[11,63–65]

Patient satisfaction research conducted with instruments described above shows that most OMT clients (virtually all, in many cases) are highly satisfied with the care received.[11,56,58,60,65] However, these findings clearly contradict a) specific comments made by particular OMT patients on many occasions and situations;[66] b) most studies that have used a qualitative methodology to explore the views and experiences of OMT clients, the results of which are more nuanced, or in some cases, reflect a clearly ambivalent attitude toward OMT;[66–69] and c) the results obtained by satisfaction surveys that include (in addition to items or a scale to evaluate satisfaction) either a list of potential problems or negative treatment-related aspects from which the respondent must select, or open-ended questions requiring a short response about which aspect(s) of the user's experience with the center he/she finds least satisfying.[25,58,70] Interestingly, these latter mixed-method studies have allowed researchers to identify significant and/or frequent problems reported by clients who, concurrently, showed a high level of satisfaction with OMT.

To explain the reasons behind this apparent discrepancy, two distinct but nonexclusive arguments can be made: one line of argument is more closely related to conceptual aspects, while the other is mostly concerned with various methodological questions.

Conceptual confusion between patient perceptions and patient satisfaction

There is a conceptual confusion originating from the interchangeable use of the terms "patient satisfaction" and "patient perceptions." Satisfaction refers to the patient's perception of the extent to which his/her expectations, needs, or desires have been met. Satisfaction is thus, a particular kind of perception, but it is not the only one.[71] This confusion has increased as most scales that assess satisfaction with addiction treatment have been developed without an underlying theoretical framework. Although various theoretical models of the "treatment satisfaction" construct exist, it seems to be assumed implicitly – and naively – that this is a construct with a universal meaning, or one that does not require greater clarification.[72] In fact, some authors believe that the concept of treatment satisfaction seems to have been imposed on service users, with little consideration of its relevance.[73] This situation is even more complex in the case of OMT, in which meanings linked to the construct of "patient satisfaction" and their respective operationalization can lead to even more confusion and ambiguity. For instance, from both a clinical and research perspective, it seems necessary to distinguish, at a minimum, between a) holding dose (ie, the dose that prevents subjective and objective opioid withdrawal symptoms over the 24-hour interdosing interval); b) dose adequacy (ie, the dose that allows patients not to use heroin, not to experience withdrawal symptoms nor heroin craving, not to show symptoms of overmedication, and in the case of heroin use, to hardly experience any subjective effects); c) satisfaction with medication; and d) satisfaction with treatment.[74,75]

Even when patients report a high degree of satisfaction with treatment, this does not necessarily entail that they have a similarly positive perception of the treatment received. High satisfaction scores can be due to negative initial expectations[25,76] or may reflect, among other nonexclusive alternatives, beliefs of the type "they do the best they can"[77,78] or "really, that is not their job",[78] or service user preference to demonstrate a positive interaction with the people who care for them (social etiquette),[79] or the limitations derived from the user's dependent position in the health care system.[79] Given the consistently positive results from patient satisfaction surveys, it is no wonder that many authors believe these types of survey are little more than rhetorical practices that provide us with the comforting illusion that we are listening to patients,[80] or that these surveys are mechanisms by which managers and clinicians seek to legitimize and maintain the status quo of treatment centers.[69,81–83]

Methodological and procedural issues

The second line of argument concerns diverse methodological and procedural issues related to satisfaction surveys.

Unidimensional versus multidimensional approaches

Patient satisfaction instruments can be classified according to factor structure as either unidimensional (ie, those that report a single overall satisfaction factor) or multidimensional (ie, comprised of several factors corresponding to differentiated facets or dimensions of treatment satisfaction).[84,85] Dissatisfaction rates are, in general, higher in surveys that use multidimensional scales compared to those obtained with surveys that have used global or unidimensional instruments,[85,86] although this comparison is not completely appropriate due to methodological differences arising from the type of instrument used.

Affective versus factual focus

Patient satisfaction scales can be divided into two types depending on the contents: factual measures (ie, objective reports) and affective measures (ie, subjective rating scales).[85,87] Factual instruments, which are designed to avoid value judgments, focus on the service user's experiences. These types of instruments contain specific questions about those experiences in order to acquire objective data ("How often do you go to the center to take or pick up methadone?"; "How long after the scheduled appointment time do you usually have to wait to be seen?") or to verify whether certain processes and specific events have occurred or not ("Have the side effects of methadone been explained to you?"). In contrast, affective instruments focus on the patient's opinion about those experiences which reflects his/her preferences and expectations ("Do you think the frequency of your visits to the center to take/pick up methadone is excessive?"; "Are you satisfied with the waiting time between the scheduled appointment time and the actual start of the appointment?"; "Are you satisfied with the information you have received about the side effects of methadone?").

There is a lack of validated factual instruments among the satisfaction scales available for use in addiction treatment and harm reduction services. However, when such instruments do become available, it seems likely that the experience observed in other health care settings – ie, affective measures typically detect higher levels of satisfaction with treatment than factual instruments[85,88] – will be repeated.

Affective self-report instruments, particularly those with a unidimensional factor structure, are unlikely to provide information that will be useful to improve health care.[85,86,89] This is due to the way that most questions are formulated in these instruments; in many cases, it is not clear what elements, aspects, or processes need to be modified when a client's response indicates dissatisfaction,[90,91] and it is even less clear how such changes should be effectuated. However, the use of multidimensional instruments (especially the factual measures) can remediate, at least partially, this weakness, as has occurred in other areas of health care.[88,92,93]

Early drop-outs and refusals to participate

We must not neglect a discussion of two important variables that have received insufficient attention in many of the patient satisfaction studies carried out to date in the addictions field: a) the number of early drop-outs from the program being evaluated[81,85,94,95] and b) the nonresponse rate to the survey.[26,96–99] Early drop-outs and no response could be reflecting low levels of satisfaction with treatment. These factors contribute to the uncertainty of the results obtained and are a threat to both the internal validity and generalizability of such results.

A variant of the Hawthorne effect

The Hawthorne effect is a positive and transitory change in a behavior being evaluated under experimental conditions. The change in behavior occurs not because of any alterations in the independent variable, but rather because participants know they are being observed or studied.[100] By analogy, levels of satisfaction with treatment could, in some cases, reflect or be sensitive to this effect. Sitzia and Wood[101] indicate that both the extra attention implicit in the process of data collection and the apparent interest in the user's level of satisfaction could lead to a positive perception of the service or center and, consequently, to higher scores.

The phenomenon of response shift

Finally, the response shift phenomenon[102] merits discussion as a potential additional explanatory factor for the high levels of patient satisfaction typically observed. This phenomenon has been widely studied in the field of health-related quality of life, although it is equally relevant to any field that uses self-report instruments.[103] Villar López et al[104] highlighted the importance of response shift in evaluating satisfaction with treatment. The response shift phenomenon in health care settings refers to the process of adaptation to changes caused by the disease or treatment.[103] More specifically, Sprangers and Schwartz[102] define response shift as a change in the meaning of the self-evaluation of the target construct as a result of a) a change in the internal standards of measure (scale recalibration); b) a change in the values themselves – in other words, in the importance of the domains or components that make up the target construct (scale reprioritization); or c) a redefinition of the target construct (reconceptualization). Many years of substance use and a relatively long OMT could potentially modify the client's internal standards, values, and/or concept of treatment satisfaction and, thereby, overestimate those levels of satisfaction.

Future directions

Most of the instruments currently available to assess user satisfaction with addiction treatment and harm reduction services are probably unable to adequately measure satisfaction due to how those instruments were developed. In general, the available instruments are based on a theoretical model that is often only vaguely defined and which evaluates areas of interest chosen by the researchers, service providers, or policy makers.[105,106] It seems evident that self-reports developed in this manner are more likely to reflect the priorities of the clinicians, researchers, and/or administrators rather than those of the service users.[101,107–109] This implies that questions about aspects of treatment and care that are relevant to patients would not be included, even though other variables that patients might consider irrelevant are incorporated.[87] If true, to some extent this represents a threat to basic bioethical principles, such as autonomy,[110] and to the validity of data gathered with these tools,[111] questioning the results obtained with these instruments.

Users of addiction treatment and harm reduction services – like users of any other health care services and programs – have a complex and highly nuanced experience that can be more appropriately and fruitfully captured via more generic, open-ended questions that are formulated in terms of the user's experience (not the satisfaction) with the service. Additional approaches include other qualitative techniques of data gathering, such as participant observation,[112,113] focus groups,[31,67] or in-depth interviews.[114–116] Likewise, the critical communicative methodology[117–119] would seem to be particularly pertinent and promising in this area of research. Although the information provided by these methods can be extremely valuable for improving and redesigning interventions, a periodic quality assessment relying heavily on these approaches appears to be of questionable practicality under current circumstances.

The use of the critical communicative methodology or qualitative data gathering techniques must be an essential requirement for developing the much-needed new scales to measure treatment satisfaction[120] or perception of treatment[121] in a more patient-centered manner (Table 2).[109,122] A genuinely patient-centered assessment of satisfaction with treatment will not be feasible without patients participating in the development of the instrument (eg, identifying the dimensions and variables to be assessed, drafting the items). Moreover, the aforementioned techniques should also play a major role in helping health professionals and researchers to directly, through the patient's own words, come to gain a thorough understanding of the patient's perspective (eg, expectations,

Table 2 Classification of instruments to measure patient satisfaction according to the degree to which they incorporate the patient's own perspective

Type	Description
Patient satisfaction scale developed by patients	A patient satisfaction scale (PSS) developed by patients (PSS-DP) is a PSS developed completely from the patients' perspective. The main differentiating characteristic of this type of PSS lies in the fact that all those involved in the different phases of its development are (or have been) recipients of the service to be evaluated.
Patient-centered satisfaction scale	A patient-centered PSS (PSS-CP) is a PSS that explicitly incorporates, to a greater or lesser extent, the patients' perspective. Even though other stakeholders (eg, clinicians, researchers, family members, and/or administrators) have participated in developing the instrument, the patients themselves have made major contributions, usually in the initial phases of 1) generating the domains or variables to be evaluated, 2) writing the questions, and/or 3) evaluating some characteristic of the initial or pilot version of the instrument (eg, pertinence or comprehensibility of the items).
Patient satisfaction scale valued by patients	A PSS valued by patients (PSS-VP) is a PSS that, developed without direct patient participation, is considered as such (ie, valued or appreciated) by most of them because it reflects, at least in part, their perspectives. To determine whether a PSS developed without patient participation can be considered patient-valued, qualitative research methods such as focus groups or cognitive interviews must be performed.
Patient satisfaction scale irrelevant to patients	A PSS irrelevant to patients (PSS-IP) is a PSS that has been 1) entirely developed without any patient participation, and 2) assessed by patients as irrelevant or of no interest or value. A priori, assuming no additional information is available, any PSS developed without any direct patient participation should be placed, at least provisionally, in this category.

Note: Data from Trujols et al.[122]

perceived participation in decision-making). Having a deeper understanding of this perspective is an essential part of any efforts to improve the quality of addiction treatment and harm reduction services. This perspective cannot and should not be limited to user satisfaction with the service, and neither should user-participation in quality improvement efforts be restricted to answering a questionnaire. That said, if planners, managers, and workers involved in addiction treatment and harm reduction services are unwilling to make the necessary effort to achieve an in-depth understanding of users' perspective – and to act on any new insights obtained in the process – then these methodologies are unlikely to be implemented, and thus, authentic patient-centered satisfaction surveys will not be carried out.

Given this situation, it is not surprising that some authors, both in the drug-use intervention field[8] as well as in other areas of health care[123] pose this question: Do current satisfaction surveys form part of an emerging process of shared decision-making whose objective is to improve health care delivery and clinical care practices or, to the contrary, are such surveys a mere token gesture (ie, an empty ritual)[124] from which no changes will emerge? In accordance, Madden et al[25] affirm that "satisfaction surveys will be of only limited value in opioid treatment settings until there are agreed quality standards and formal mechanisms to educate consumers about their rights and the standards of care to which they are entitled". Without these changes and a commitment to act on the knowledge so acquired, it is unlikely that meaningful, rather than tokenistic, modalities of user involvement will be widely implemented in the near future. In fact, service users should not be asked to participate in a satisfaction survey if their input will amount to nothing. Moreover, it should be also emphasized that the aforementioned changes are unlikely to increase the right of service users to participate if their most basic needs are not met.

Patient participation should extend beyond assessing and improving the quality of care. The involvement of drug/service users in the design and implementation of specific programs and interventions, especially in the field of harm reduction, has been remarkable, with users, at times, displaying a higher level of competence than the public health institutions themselves.[125–127] Similarly, considering that users' rights should not be limited to treatment needs alone,[128,129] this dialogical and participatory dynamic should be extended to other areas such as addiction research[130] and the development of drug policies.[131]

Limitations

The aim of this article was to provide a critical review of a comprehensive topic (ie, satisfaction with addiction treatment and harm reduction services) rather than a systematic examination of a focused research question. Therefore, a nonsystematic review was judged as the best approach for covering a wide range of issues relating to the topic reviewed. However, this approach implies not to systematically identify, select, appraise, and synthesize all research on the topic, representing a possible limitation of the present study. In any case, as several authors have pointed out, traditional narrative reviews are more appropriate for comprehensive topics and systematic reviews are better suited for focused topics.[132] Additionally, our attempts to identify relevant studies went beyond the efforts usually made in narrative reviews. Spanning the last decade, our experience in research on satisfaction with addiction and harm reduction services[5,8,11,26,29,32,57,58,74,75] has rendered us current on this topic. In this regard, the PubMed interface to search MEDLINE has been used. A search strategy favoring sensitivity over specificity is periodically performed using different combinations of addiction (eg, substance abuse, heroin, cocaine) or intervention-specific (eg, methadone, detoxification, needle exchange) terms and words related to the patient's perspective (eg, satisfaction, perception, view). In addition, reference lists included in the selected articles are normally examined for other relevant studies.

Conclusion

The current approach to user satisfaction surveys does not significantly contribute to the improvement of service quality. Therefore, most of the enthusiasm and naiveté with which user satisfaction surveys are currently conducted and interpreted – and rarely acted on in cases of nonoptimal results – in addiction treatment and harm reduction services should be avoided. A truly participatory approach to program evaluation is needed urgently to reshape and transform patient satisfaction surveys. Similarly, there is a need to implement alternative research and quality-improvement initiatives that foster meaningful, rather than merely tokenistic, service user involvement. In turn, this will surely improve the relevance as well as the psychopolitical validity (both epistemic and transformative)[133,134] of research and interventions in the substance use field.

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Author contributions

Joan Trujols and Ioseba Iraurgi conceived of and designed the present study, counting on advice from Eugenia Oviedo-Joekes and Joan Guàrdia-Olmos. Joan Trujols wrote the initial draft and led the writing of subsequent versions. All authors commented on and significantly contributed to the successive drafts. All authors read and approved the final version submitted for publication.

Disclosure

The authors state that they have been involved in the design, implementation, analysis, and/or reporting of satisfaction survey studies, whether or not cited in the current manuscript. Joan Trujols also declares to be a member of the team of researchers who adapted the Verona Service Satisfaction scale for methadone treatment programs; this adaptation is, in any case, in the public domain. Authors do not consider these facts to constitute actual or potential conflicts of interest with respect to the submitted manuscript but include the information for completeness and transparency. The views expressed are those of the authors and do not necessarily represent nor reflect those of the organizations or institutions in which they work. The authors report no other conflicts of interest in this work.

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Trujols, J., Iraurgi, I., Batlle, F., Duran-Sindreu, S. i Pérez de los Cobos, J. (2015). Towards a genuinely user-centred evaluation of harm reduction and addiction treatment programmes: A further proposal. *International Journal of Drug Policy*, *26*, 1285-1287.

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Viewpoint

Towards a genuinely user-centred evaluation of harm reduction and drug treatment programmes: A further proposal

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Assessing the outcomes of social and health interventions is a complex process. Assessment must consider conceptual, ethical, clinical, and logistical factors, amongst others issues (Thornicroft & Slade, 2014). Harm reduction and drug treatment programmes provide an excellent example of the challenges involved in selecting appropriate tools and measures of intervention efficacy and effectiveness. Indeed, the ongoing debate in the literature (e.g., Donovan et al., 2012; Tiffany, Friedman, Greenfield, Hasin, & Jackson, 2012) serves to underscore this point. Importantly, an essential aspect of treatment outcome, which has received scant attention, is the perspectives of service-users or patients. This oversight is particularly concerning given that the views of service users with regards to desirable or successful treatment may be very different from the views held by treatment professionals.

This divergence of views between health care providers and patients has been documented in multiple studies. For example, one qualitative study, published nearly 20 years ago, found that the treatment objectives of a large percentage of heroin users who entered methadone maintenance treatment (MMT) differed substantially from those ascribed to such patients by classical professional models (Koester, Anderson, & Hoffer, 1999). Another study compared patient-perceived to clinician-rated improvement in MMT, finding only a weak correlation between the two perspectives (Trujols et al., 2011). This discrepancy between clinicians' and patients' perceptions of improvement is consistent with results obtained from a substance misuse counselling service (Pulford, Adams, & Sheridan, 2009). In a different study, researchers used focus groups to explore the construct of quality of life (QoL) as perceived by drug users. The findings revealed that drug users' views of QoL encompass more domains (e.g., interpersonal relationships, social inclusion, and self-determination) than those typically included in health-related QoL instruments (de Maeyer, Vanderplasschen, & Broekaert, 2009). Finally, a recently published study identified a clear gap between the views of service users and service providers in terms of the measures that should be used to assess recovery from drug addiction (Neale et al., 2015). An inherent caveat of the findings presented above is that neither the perspective of the service user nor that of the service provider should be considered monolithic and univocal (McKeganey, Morris, Neale, & Robertson, 2004; Neale, Nettleton, & Pickering, 2011; Neale et al., 2015).

By taking into account the perspectives of both treatment professionals and service users, it is possible to obtain useful, complementary information on treatment outcome, as other authors have pointed out (e.g., Thornicroft & Slade, 2014). In this context, the authors of an editorial recently published in the International Journal of Drug Policy (Alves, Sales, & Ashworth, 2015) are to be commended for their "personalised outcome measurement approach", a potentially valuable assessment methodology that combines standardized and individualized outcome measures (IOMs). However, it is important to point out that, in terms of the degree of patient involvement, standardized outcome measures (SOMs) are not as homogeneous as that editorial seems to imply.

Broadly speaking, SOMs can be divided into two main categories based on how information is gathered: (1) clinician-rated (mainly interview-administered questionnaires and structured and semi-structured interviews) and (2) self-reported instruments (primarily self-administered questionnaires, scales, and inventories). Although a clinician-rated outcome measure can theoretically be patient-centred without being patient-reported (Basch, Abernethy, & Reeve, 2011; Methodology Committee of the Patient-Centered Outcomes Research Institute, 2012), virtually all clinician-rated instruments focus on outcome variables prioritized by policy makers, service managers, clinicians, and/or researchers—in other words, such instruments are usually developed without patient input. By contrast, self-reported SOMs (also known as completely-standardized, patient-reported outcome measures [PROMs] in the terminology proposed by Valderas and Alonso (2008)) provide a more nuanced and variegated picture of patient outcomes, depending on the extent to which the instrument incorporates patient perspectives. This is particularly true in the mental health field, but also to a lesser extent in harm reduction and addiction treatment.

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Given this background, and acknowledging that not all completely-standardized PROMs capture or reflect patient perspectives (Trujols & Portella, 2013), our group developed a system to classify these outcome measurement instruments according to the degree to which they genuinely incorporate and measure patient perspectives (Trujols et al., 2013). This taxonomic system divides completely-standardized PROMs into four distinct categories, as follows: (1) *Patient-generated PROMs* (PG-PROMs), a type of PROM that has been developed completely from the service-user's perspective given that all the individuals involved in the development of the PG-PROMs are, or have been, recipients of the intervention or treatment to be evaluated (Rose, Evans, Sweeney, & Wykes, 2011); (2) *Patient-centred PROMs* (PC-PROMs), a type of PROM whose contents explicitly reflect, to a greater or lesser degree, patient perspectives, because the patients have made major contributions to the development of the instruments (e.g., by choosing which domains or variables should be evaluated; drafting the items; and/or assessing their relevance and comprehensibility); (3) *Patient-valued PROMs* (PV-PROMs), a variety of PROM that, although developed without direct patient participation, is valued or appreciated by most patients because it reflects—at least to some extent—their perspectives (Kabir & Wykes, 2010); (4) *Patient-irrelevant PROMs* (PI-PROMs), a type of PROM that has been entirely developed without patient involvement and which has been subsequently evaluated by patients who deem it to be irrelevant or of no value. This classification system takes into account the fact that, in the development of a user/patient-centred approach to outcomes assessment, there are essentially only two real alternatives: (1) outcomes that more authentically focus on and reflect user/patient related experiences, concerns or values; (2) outcomes that are developed or defined in a genuinely participatory approach with/by users. This distinction is very relevant because outcome measures from these two categories are not necessarily interchangeable. In fact, PC-PROMs and PG-PROMs can be very different instruments in terms of the degree to which they incorporate and capture patient perspectives and values. Truly participatory, user-focused methodologies (and even user-led research) are necessary to develop PROMs that can measure outcomes that are genuinely relevant to patients/service-users.

To our knowledge, no PG-PROMs have been developed to assess harm reduction interventions or addiction treatments. However, the methodology for developing this type of PROM—established and standardized by the Service User Research Enterprise at the Institute of Psychiatry in London (Rose et al., 2011)—has already proven successful in the field of rheumatoid arthritis (Hofmann et al., in press) and is surely transferrable to outcomes research in harm reduction and addiction treatment services. Likewise, with regards to PV-PROMs, we know of no studies that have evaluated widely-used PROMs to assess their relevance (and content-appropriateness) to service-users. The dearth of research in this area is regrettable because such work can yield highly enlightening findings, as similar studies have found in the field of mental health (Crawford et al., 2011). Despite the scarcity of research on PV- and PG-PROMs in harm reduction and addiction treatment programmes, it should be noted that a limited but non-negligible number of standardized evaluation models and PC-PROMs that meaningfully incorporate concerns of service users have already been developed in the harm reduction field (e.g., Lee & Zerai, 2010; Ruefli & Rogers, 2004). Similarly, a small but increasing number of studies are contributing to the knowledge base for developing PC-PROMs in the area of addiction treatment (e.g., Lozano Rojas, Acedos Bilbao, González Saiz, & Ballesta Gómez, 2008; Thurgood, Crosby, Raistrick, & Tober, 2014). Indeed, several instruments (e.g., Luquiens et al., 2015) are available for use.

It is essential to realize that a lack of patient-relevant outcome measurement instruments—whether these tools are standardized (PG- and PC-PROMs) or individualized (IOMs)—can lead to incomplete, if not misleading, information that problematizes any evaluation of a treatment or intervention (Fischer, Rehm, & Kim, 2001). For this reason, it is imperative, as other authors have previously suggested (e.g., Alves et al., 2015), that the range of outcome instruments include "a fair balance of those conventionally derived and those developed from a service user perspective" (Rose et al., 2011, p. 41). In fact, in certain areas of outcomes research (e.g., Absolom, Holch, Woroncow, Wright, & Velikova, 2015; Patrick et al., 2011; Staniszewska, Haywood, Brett, & Tutton, 2012), there seems to be an increasing—and long-overdue—consensus that patients should be meaningfully involved in the development of any new PROM through truly participatory research approaches. Indeed, this growing consensus is in line with the widely-accepted principle (and evidence-supported practice) in harm reduction initiatives: "Nothing about us without us" (Jürgens, 2008; Marshall, Dechman, Minichiello, Alcock, & Harris, 2015).

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Conflict of interest statement

All authors declare no financial interests or potential conflicts of interest that could inappropriately influence, or be perceived to influence, this work.

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5.

Discussió

En aquest apartat, després d’una breu introducció, discutim els principals resultats o aportacions dels sis estudis/treballs que componen aquesta tesi. Aquesta discussió és desenvolupada, en un primer moment, de forma seqüencial (és a dir, treball a treball) i, posteriorment, de forma més global o integrada. Així, l’ordenació o lògica mateixa de la discussió —tal com l’hem plantejada— comporta situar el subapartat de punts forts i limitacions just abans de la discussió general, atès que l’esmentat subapartat fa referència a particularitats dels estudis individuals o dels blocs diferenciats de treballs (estudis empírics *vs*. articles teòrics) i no, amb una sola excepció, a característiques globals o compartides pel conjunt dels sis treballs.

Tot i que la recerca sobre la perspectiva de la persona en TMM havia despertat un cert interès al llarg dels darrers dos decennis, la majoria d’estudis realitzats s’havien centrat en la QVRS dels pacients en TMM. Així mateix, en el cas dels treballs vinculats amb la perspectiva del pacient sobre el TMM, es tractava d’estudis que majoritàriament —per no dir en la pràctica totalitat dels casos—: *a*) avaluaven la satisfacció amb el TMM amb instruments genèrics i unidimensionals; *b*) avaluaven únicament la satisfacció amb el TMM i no la seva relació amb altres resultats comunicats pels pacients, com, per exemple, la millora percebuda; *c*) no diferenciaven a l’hora de l’avaluació entre la satisfacció amb la metadona com a fàrmac i la satisfacció amb els altres processos/components del TMM o del centre de tractament; *d*) no emfatitzaven la identificació de factors predictors o explicatius de la satisfacció amb el TMM; i *e*) no es qüestionaven, tot i que es tractava de l’avaluació de variables eminentment subjectives, fins a quin punt els instruments de mesura disponibles estaven realment centrats en el pacient en TMM, és a dir, fins a quin punt avaluaven el constructe en qüestió tal com el definiria i l’operativitzaria l’usuari mateix.

El treball inicial d’aquesta tesi representa el primer estudi publicat que ha avaluat específicament la concordança entre les valoracions de millora realitzades per dos membres de l’equip clínic (psiquiatre i infermera) i la realitzada pel pacient en TMM. Els resultats mostren que la millora global avaluada pel pacient: *a*) presenta una escassa concordança amb les avaluacions realitzades pels clínics; i *b*) no està relacionada amb la seva satisfacció amb el TMM.

Aquesta discrepància clínic-pacient pel que fa a la millora percebuda, coherent amb les troballes d'estudis similars duts a terme en l'àmbit de les addiccions (Pulford, Adams i Sheridan, 2009) i de la salut mental (Weiss, Rabinowitz i Spiro, 1996), és un exemple il·lustratiu d'allò que s'ha anomenat la *paradoxa de la dessincronia* (Bilsbury i Richman, 2002), és a dir, l'absència o escassa correlació entre els resultats avaluats des de diferents perspectives. De fet, estudis de característiques semblants i realitzats al llarg dels darrers 35 anys mostren com aquesta paradoxa abasta tot l'àmbit de l'atenció a la salut (Dreyer, Jones, Kutty i Spertus, 2016; Nelson et al., 1983). Així, Dreyer et al. (2016), mitjançant una metodologia molt similar a la nostra —un mateix instrument d'ítem únic, administrat de manera independent al clínic i al pacient, per avaluar el canvi global des de la visita inicial—, mostren una discordança substancial entre les perspectives del cardiòleg i les del pacient amb insuficiència cardíaca congestiva a l'hora de quantificar el canvi al llarg d'un període de sis setmanes. Tal com suggerien fa més de tres decennis Nelson et al. (1983), podria ser que l'avaluació del clínic es faci en termes de *disease* mentre que la del pacient es basi en la mètrica de la *illness*.

Sigui com sigui, aquesta escassa concordança clínic-pacient no es limita a la valoració del canvi o millora, sinó que abasta la definició i l'operativització de diversos constructes vinculats amb l'avaluació dels TMM —i de moltes altres intervencions de l'àmbit dels trastorns addictius— com, per exemple, la retenció en tractament (Mitchell et al., 2009), el concepte de recuperació o restabliment (Neale et al., 2015) o la noció mateixa d'èxit *vs*. fracàs terapèutic (Room, 2012). De fet, res de tot això ens hauria d'estranyar si tenim en compte que, tal com afirmen Magura et al. (1988, p. 255) referint-se específicament als TMM, «the various goals pursued by administrators, line staff, and patients, which are based on factors such as community expectations, program objectives, and individual needs, may not always be entirely compatible».

Així mateix, l'absència de relació entre la millora percebuda pel pacient en TMM i la seva satisfacció amb el tractament és coherent, tal com s'especifica amb detall a la discussió de l'article, amb els resultats d'estudis realitzats tant en el context dels TMM (Perreault et al., 2010) com en l'àmbit de l'atenció a la patologia dual (Ries, Jaffe, Comtois i Kitchell, 1999), i suggeriria que es tracta de dues variables que representen aproximacions diferenciades a la perspectiva del pacient en TMM.

En estreta relació amb aquest punt, cal destacar els resultats de l'estudi de Rademakers, Delnoij i de Boer (2011) en el qual van participar diversos grups de pacients amb patologies mèdiques força diferents (per exemple, cataracta o artritis reumatoide). Aquest estudi mostra que els aspectes concrets de l'atenció a la salut amb més capacitat explicativa de la puntuació global atorgada pel pacient a la qualitat de l'atenció rebuda són els aspectes vinculats amb el procés, seguits dels relatius a l'estructura i, finalment, els relacionats amb els resultats de l'atenció. En aquesta mateixa línia, alguns autors recomanen que els instruments de mesura de la satisfacció del pacient diferenciïn clarament la satisfacció amb la provisió del tractament de la satisfacció amb el seu resultat (Fontana, Rosenheck, Ruzek i McFall, 2006).

El segon estudi és fruit del primer intent d'utilitzar en l'àmbit dels TMM un instrument —el TSQM— dissenyat per a l'avaluació genèrica i multidimensional de la satisfacció amb qualsevol medicament. Els resultats obtinguts mostren la fiabilitat i validesa de les puntuacions de la versió espanyola del TSQM 1.4 en una mostra de pacients en TMM. Pel que fa a les evidències de validesa convergent, cal remarcar-ne, tal com s'explicita amb més detall a la discussió de l'article, la congruència amb les hipòtesis plantejades i, especialment, la correlació moderada entre les puntuacions globals del TSQM i de la VSSS-MT. La grandària de l'efecte d'aquesta correlació suggeriria —tal com plantejàvem en la nostra diferenciació teòrica entre *holding dose*, adequació de la dosi, satisfacció amb la metadona com a fàrmac i satisfacció amb el TMM (Trujols, Siñol i Pérez de los Cobos, 2010)— que la satisfacció amb la metadona com a medicament i la satisfacció amb el TMM són dues variables, tot i que relacionades en cert grau, diferenciades. En aquesta mateixa línia, hem desenvolupat recentment un instrument per avaluar de manera multidimensional però específica la satisfacció amb la metadona com a medicament per al tractament de la dependència d'heroïna (Pérez de los Cobos, Trujols, Siñol i Batlle, 2014).

Desconeixem l'existència d'altres estudis que hagin avaluat el comportament psicomètric del TSQM 1.4 no només en el cas dels TMM, sinó també en el dels altres múltiples tractaments o intervencions implementats en l'àmbit de l'atenció als trastorns addictius. De fet, en aquest àmbit i fins a l'actualitat, el TSQM 1.4 s'hauria utilitzat únicament —a banda del nostre estudi— per avaluar la satisfacció amb el tractament amb baclofèn en pacients dependents de l'alcohol (Heydtmann et al., 2015).

Aquesta manca d'estudis és especialment significativa si tenim en compte que el TSQM 1.4 és un dels escassos instruments genèrics existents per a l'avaluació multidimensional de la satisfacció amb qualsevol tractament farmacològic (Katusiime, Corlett, Reeve i Krska, 2016) i ha generat força estudis psicomètrics en el marc de múltiples patologies mèdiques com, per exemple, la fibrosi quística (Regnault, Balp, Kulich i Viala-Danten, 2012), la hipertensió arterial (Liberato, Rodrigues, Kim i Mallory, 2016) o l'esclerosi múltiple (Vermersch et al., en premsa).

El tercer treball, darrer del bloc d'estudis anomenats *empírics* per l'American Psychological Association (2010), destaca pel fet de ser una de les primeres recerques sobre el nivell de satisfacció amb el TMM d'una mostra representativa de pacients d'un àmbit territorial concret que ha incorporat —entre els potencials predictors avaluats— un instrument de cribratge psicopatològic. Cal destacar especialment per la seva robustesa, derivada del fet d'haver-se obtingut mitjançant dues tècniques d'anàlisi multivariable diferenciades però complementàries, el resultat relatiu a les variables associades de forma independent amb el nivell de satisfacció amb el TMM. Els resultats obtinguts mostren que pacients tractats en centres amb un nombre més elevat d'usuaris, que es perceben a si mateixos com a participants en certa manera actius a l'hora de prendre decisions relatives al tractament i que presenten un menor deteriorament pel que fa a funcionament psicosocial, es mostren més satisfets amb el TMM.

Considerant la capacitat —és a dir, el nombre d'usuaris atesos— del centre de tractament, tal com es discuteix específicament a l'article, com un indicador de la disponibilitat de serveis auxiliars, l'associació observada entre aquesta capacitat i el nivell de satisfacció amb el TMM és esperable, atesa la rellevància d'aquest tipus de serveis per a un percentatge important de pacients en TMM (per exemple, McLellan, Arndt, Metzger, Woody i O'Brien, 1993; Puigdollers, Cots, Brugal, Torralba i Domingo-Salvany, 2003). No obstant això i pel que fa a l'eventual eficàcia addicional d'incorporar intervencions psicosocials al TMM, els resultats no són concloents. Una revisió sistemàtica recent assenyala que, globalment, els estudis revisats mostren la utilitat de les intervencions psicosocials en el context del TMM (Dugosh et al., 2016), mentre que la síntesi metaanalítica realitzada per la Col·laboració Cochrane conclou que afegir qualsevol intervenció psicosocial al TMM no aporta beneficis addicionals (Amato, Minozzi, Davoli i Vecchi, 2011).

Així mateix, l'associació igualment significativa i positiva entre participació percebuda en la presa de decisions i satisfacció amb el tractament és coherent amb els resultats d'estudis realitzats en el context dels TMM o d'altres modalitats de tractament en l'àmbit de les addiccions, i publicats abans (Brener, Resnick, Ellard, Treloar i Bryant, 2009; Fischer, Jenkins, Bloor, Neale i Berney, 2007) o després (Marchand et al., 2015; Vanderplasschen et al., 2015) del nostre. Aquesta associació és igualment omnipresent en l'àmbit més general de l'atenció a la salut mental (per exemple, Clarke et al., 2015; Tambuyzer i Van Audenhove, 2015).

Finalment, l'associació inversament proporcional entre deteriorament en el funcionament psicosocial (subescala de disfunció social del GHQ-28) i satisfacció amb el TMM podria explicar-se pel fet que els pacients amb més problemes pel que fa a funcionament psicosocial consideressin que una de les seves principals necessitats de tractament és coberta de manera insuficient pel TMM tal com és implementat. De fet, l'associació entre la presència de comorbiditat psiquiàtrica i menor satisfacció amb el tractament és corroborada per diferents estudis duts a terme en altres àmbits del tractament dels trastorns per consum de substàncies psicoactives, i publicats amb anterioritat (Boden i Moos, 2009; Urbanoski, Rush, Wild, Bassani i Castel, 2007) o posterioritat (A. L. Jones et al., 2015; Zhang et al., 2016) al nostre.

El quart article i primer dels tres de caràcter no empíric —o, seguint la normativa APA (American Psychological Association, 2010), *articles teòrics*—, després de destacar breument l'escassetat d'estudis que realment incorporen la perspectiva del pacient a l'hora d'avaluar l'efectivitat del TMM, proposa una possible classificació de les MRCP en funció del nivell de participació del pacient mateix en el procés de disseny i desenvolupament de l'instrument. En un ordre de més a menys reconeixement i implicació dels pacients en aquest procés, la taxonomia proposada distingeix entre els següents tipus de MRCP: *a*) les generades pels pacients mateixos (MRCP-GP), instruments en els quals totes les persones implicades en les diferents fases del seu desenvolupament són o han estat receptores de la intervenció objecte d'avaluació; *b*) les centrades en el pacient (MRCP-CP), instruments que incorporen volgudament la perspectiva dels pacients atesa la seva participació en les fases inicials de desenvolupament; *c*) les valorades pel pacient (MRCP-VP), instruments que, tot i que s'han desenvolupat sense la participació dels pacients, són considerats pertinents o adequats per una majoria d'aquests pacients perquè reflecteixen en certa manera les seves perspectives; i *d*) les irrellevants per al pacient (MRCP-IP), instruments desenvolupats sense la participació directa dels pacients que són avaluats com a no rellevants o mancats d'interès per part dels pacients mateixos.

En rigor, tot i que aquesta consideració és posterior a la publicació de l'article en qüestió, caldria esmentar que un dels nivells d'aquesta classificació, concretament el que correspon a les MRCP-CP, és poc específic. D'acord amb Lasch et al. (2010), fer més o menys èmfasi en el component qualitatiu —habitualment grups focals o entrevistes en profunditat— subjacent a les fases inicials de desenvolupament de l'instrument comporta una notable variabilitat a l'hora d'incorporar realment la perspectiva del pacient. En aquesta línia, Magasi et al. (2012) afirmen que el pes relatiu de les aportacions dels pacients —respecte al de les realitzades pels altres agents implicats en el desenvolupament de l'instrument de mesura— és una qüestió central en el debat sobre l'evidència de validesa basada en el contingut: «Even when patient input is used to develop item content, someone must decide what remains and what is removed from a questionnaire» (p. 741). Així doncs, podria ser d'especial interès una subdivisió de les MRCP-CP a partir de tres dels nivells de la classificació proposada per Sweeney i Morgan (2009) per caracteritzar el grau de participació del pacient en qualsevol recerca: consulta, contribució i col·laboració.

Tot i que les conseqüències sobre el contingut de les MRCP derivades de la participació o no dels pacients en el seu procés de desenvolupament són conegudes des de fa, si més no, 30 anys (Lomas, Pickard i Mohide, 1987; Rat et al., 2007), ens consta l'existència d'una única tipologia que tingui en compte —com a eix classificatori o com una dimensió o categoria a considerar— el nivell de participació del pacient en la construcció de l'instrument. Es tracta de l'esquema classificatori proposat per Haywood, Staniszewska i Chapman (2012) i derivat del contínuum de participació plantejat per Boote, Telford i Cooper (2002), que formen els tres nivells següents: *a*) consulta, *b*) col·laboració i *c*) lideratge per part dels pacients. Les MRCP-GP i les MRCP-CP de la nostra taxonomia correspondrien al nivell *c* i als nivells *a* i *b*, respectivament, de la proposta de Haywood et al. (2012).

Cal esmentar també, atesa la menció que fa a la possibilitat d'una avaluació de resultats més personalitzada, el sistema classificatori desenvolupat per Valderas i Alonso

(2008). La tercera categoria del tercer eix d'aquest sistema classificatori de les MRCP és l'*adaptabilitat*, és a dir, el grau en què l'instrument pot adaptar-se a les circumstàncies i preferències de cada persona avaluada. En funció d'aquesta categoria o característica, les MRCP poden diferenciar-se en *a*) completament individualitzades, *b*) parcialment individualitzades i *c*) completament estandarditzades. Amb tot, la gran majoria de MRCP són instruments completament estandarditzats: contenen preguntes/ítems explícitament formulats i opcions de resposta predefinides.

Aquesta manca de tipologies o classificacions que tinguin en compte la participació del pacient com a eix o variable a considerar reflecteix, molt probablement, l'escàs èmfasi posat tradicionalment en aquest aspecte del desenvolupament de les MRCP. La pràcticament nul·la atenció que les eines actuals de valoració de la qualitat de les MRCP dediquen a l'avaluació de la participació del pacient en el procés de desenvolupament de les MRCP (Barr i Elwyn, 2016) semblaria corroborar la nostra interpretació. Val a dir, però, que la nova versió —no publicada encara— d'una d'aquestes eines, concretament la desenvolupada per la iniciativa COSMIN (*COnsensus-based Standards for the selection of health Measurement INstruments*; Terwee et al., 2012), farà un èmfasi especial en aquesta qüestió (Mokkink, Prinsen, Bouter, Vet i Terwee, 2016).

El cinquè treball consisteix en una revisió crítica dels estudis o enquestes de satisfacció amb el TMM. A partir d'una doble línia d'anàlisi de les limitacions d'ordre conceptual —per exemple, confusió derivada de la utilització de manera intercanviable dels termes *satisfacció del pacient* i *percepció del pacient*— i de caràcter metodològic —per exemple, aproximacions unidimensionals i afectives— presentades per aquest tipus d'estudis, s'argumenta que les enquestes de satisfacció, tal com s'implementen majoritàriament en l'actualitat, no tenen pràcticament cap paper rellevant a l'hora de millorar la qualitat dels TMM.

Desconeixem l'existència de revisions similars no només en el cas dels TMM, sinó també en el d'altres intervencions o tractaments de l'àmbit de l'atenció als trastorns per consum de substàncies psicoactives. No obstant això, la majoria de les consideracions crítiques fetes en la nostra revisió són coherents amb força aportacions de revisions igualment crítiques —vinculades, però, a l'àmbit més general de l'atenció a la salut— tant amb el constructe mateix de satisfacció amb el tractament (per exemple, Batbaatar, Dorjdagva, Luvsannyam i Amenta, 2015; Gill i White, 2009) com amb els instruments de mesura d'aquest constructe (per exemple, Hudak i Wright, 2000; Weaver et al., 1997).

El sisè article vol servir de crida per a una avaluació dels PRD o de qualsevol modalitat de tractament en l'àmbit de les addiccions, veritablement rellevant des de la perspectiva de les persones ateses. S'emfatitza la necessitat de desenvolupar i incloure en els estudis d'efectivitat MRCP realment orientades als usuaris o pacients (MRCP-GP i MRCP-CP), amb l'objectiu que en el ventall d'instruments utilitzats hi hagi un equilibri entre els instruments desenvolupats de manera habitual —és a dir, amb una participació limitada dels pacients— i les MRCP dissenyades amb metodologies veritablement participatives o, fins i tot, mitjançant estudis liderats pels pacients mateixos (Rose, Evans, Sweeney i Wykes, 2011; Vayena et al., 2016).

Una altra línia de treball compatible i coherent amb l'esmentada crida és la vinculada amb les MRCP individualitzades —també anomenades *personalitzades* o *ideogràfiques*. El màxim exponent d'aquesta línia en l'àmbit de les addiccions són els treballs del grup de Paula Alves (Alves, Sales i Ashworth, 2013, 2015, 2016). En qualsevol cas, una manca de MRCP rellevants per al pacient —ja siguin aquests instruments estandarditzats o individualitzats— pot portar a disposar d'una informació incompleta, si no errònia, que problematitzi l'avaluació de qualsevol tractament o intervenció (Fischer, Rehm i Kim, 2001).

5.1. Punts forts i limitacions

Tot i que els aspectes metodològics dels diferents estudis s'han discutit a bastament en cadascun dels articles inclosos en aquesta tesi, a continuació es comentaran els punts forts i les limitacions més rellevants o comuns a cadascun dels dos blocs d'articles.

Com a punt fort comú als tres estudis del primer bloc, cal destacar la utilització d'una escala —la VSSS-MT— dissenyada, en el nostre àmbit geogràfic de referència, per a l'avaluació de la satisfacció amb el TMM de manera específica i multidimensional (Pérez de los Cobos et al., 2002). No obstant això, la mateixa escala podria, a la vegada, no ser un instrument òptim per a una avaluació de la satisfacció amb el tractament realment centrada en el pacient perquè els pacients en TMM no van participar en el procés de desenvolupament de la VSSS-MT ni van avaluar la seva pertinència o rellevància *a posteriori*. Una altra limitació comuna al primer bloc —i, per què no anticipar-ho, també al segon— rau en el fet que cap pacient en TMM ha format part de l'equip investigador. Pel que fa respectivament a cadascun dels tres estudis, cal assenyalar com a punts forts: *a*) la utilització de versions paral·leles d'un mateix instrument —és a dir, l'Escala d'Impressió Clínica Global de Millora segons el pacient i l'Escala d'Impressió Clínica Global de Millora— per avaluar, des de la perspectiva tant del pacient com del clínic, el canvi experimentat pel pacient des de l'inici del TMM; *b*) l'heterogeneïtat de la mostra quant a diverses variables —per exemple, dosi de metadona, consum d'altres substàncies psicoactives, durada de l'episodi actual de TMM—; i *c*) l'accés a una mostra representativa de pacients en TMM. Pel que fa a limitacions específiques a cadascun dels tres estudis, cal assenyalar: *a*) el fet d'haver-se realitzat en un únic centre de TMM; *b*) el procediment de mostreig utilitzat; i *c*) el fet que el GHQ-28 no és pròpiament un instrument diagnòstic i només avalua simptomatologia no psicòtica, respectivament.

Pel que respecta als tres articles del segon bloc, la limitació principal —inherent a qualsevol article teòric— rau en la naturalesa eminentment subjectiva de qualsevol procés de desenvolupament fonamentat d'un argument o proposta. Així mateix, tal com destacava negativament —pel potencial biaix— un dels revisors d'un article d'aquest segon bloc —concretament l'article sobre la revisió crítica dels estudis o enquestes de satisfacció—, en cap no s'ha fet pròpiament una revisió sistemàtica de la literatura pertinent. No obstant això, es va optar, volgudament, per aquest altre tipus de revisió —especialment en el cas de l'article esmentat però també en el cas dels altres dos d'aquest segon bloc— perquè es va considerar que una revisió que promogués una anàlisi crítica i una clarificació conceptual era oportuna i potencialment més útil que una —conceptualment acrítica— revisió sistemàtica. A més a més, cal destacar que cap anàlisi i síntesi d'evidències està exempta de nombrosos judicis de valor (Strech i Tilburt, 2008) i que fins i tot la interpretació dels resultats de les síntesis metaanalítiques derivades de les revisions sistemàtiques d'assaigs clínics inclou també un component subjectiu que pot conduir a conclusions discordants independentment de la metodologia utilitzada per obtenir o analitzar les dades (Shrier et al., 2008). De fet, cal recordar que les metaanàlisis mateixes no deixen de ser estudis observacionals (Berlin i Golub, 2014; Kaizar, 2005).

Com a punts forts del conjunt dels treballs presentats en aquest segon bloc, cal destacar-ne el caràcter en certa manera innovador i l'èmfasi en la perspectiva de pacient. Com assenyala Berwick (2009, p. 555), «patient-centeredness is a dimension of health care quality in its own right, not just because of its connection with other desired aims, like safety and effectiveness».

5.2. Seguint amb la discussió

Arribats a aquest punt, és a dir, havent qualificat fa ben poques línies un mateix fet —concretament la utilització de la VSSS-MT— de *punt fort* —tenint en compte la seva especificitat i multidimensionalitat— i, a la vegada, de *limitació* —atesa la no-participació dels pacients en el seu desenvolupament—, es fa difícil no assenyalar —si és que no era prou palès amb anterioritat— que els objectius dels diferents estudis/treballs —tal com s'han especificat en l'apartat corresponent d'aquesta tesi i tal com consten en els respectius articles— no estaven establerts en bloc i des d'un inici per ser abordats de manera seqüencial. Tal com esmentàvem en l'apartat inicial d'aquesta tesi, els treballs presentats —de fet, el moment/text de la tesi mateixa— són l'expressió dels resultats de diverses fases d'una línia de recerca, iniciada fa més d'una quinzena d'anys, que avui encara continua. Podem afirmar, amb tota rotunditat, que no ens hauríem plantejat la necessitat d'escriure els articles que componen el segon bloc sense l'experiència —amb l'amalgama i l'encaix de vivències i coneixements que comporta el terme— d'haver dut a terme els estudis empírics corresponents al primer bloc. No obstant això, hi deu haver qui no hauria necessitat aquesta experiència, però també qui consideri que les línies argumentals i les recomanacions del segon bloc d'articles són tendencioses o, fins i tot, delirants. En qualsevol cas, aquests articles representen etapes diferenciades però recents de la nostra línia de recerca en aquest àmbit. De fet, i tornant a l'escala esmentada al principi d'aquest paràgraf, la VSSS-MT, malgrat que se'n desconeix el grau de centralitat en el pacient, continua representant un substancial avenç respecte a les escales genèriques i/o unidimensionals, instruments utilitzats encara actualment —a causa probablement de la seva brevetat— en l'àmbit dels TMM (per exemple, Marchand et al., 2015).

Considerant els resultats dels sis treballs en la seva globalitat, se'n desprèn la necessitat, la possibilitat i la rellevància de combinar, és a dir, utilitzar conjuntament i complementàriament, indicadors tradicionals/habituals —clínics i d'altra índole— i indicadors basats en la perspectiva dels pacients. Així mateix, en el cas d'aquests darrers indicadors, i atès que ningú no està més ben situat que el pacient mateix a l'hora d'aprehendre el seu propi punt de vista, una condició necessària per a un òptim procés de creació i desenvolupament dels instruments de mesura dels esmentats indicadors rau en la participació dels pacients o usuaris en les diferents fases d'aquest procés. Tal com destaquen Bilsbury i Richman (2002), buscar la virtut psicomètrica és inútil si l'instrument està tan mal enfocat que és irrellevant per al pacient.

Ni la utilització conjunta i complementària dels dos tipus d'indicadors esmentats, ni la participació dels pacients en les diferents fases del desenvolupament de noves MRCP són, però, processos de fàcil implementació. No ens referim, amb aquesta afirmació, a aspectes de tipus logístic, econòmic o de formació, totes qüestions més fàcils de resoldre en condicions mínimament favorables. Ens referim, en primer lloc, a les arrels o als enfocaments subjacents a ambdós tipus d'indicadors, orígens força diferenciats que poden afavorir una polarització estèril. Mentre que els indicadors més clàssics estan focalitzats en el trastorn i presenten una compatibilitat especial amb el model mèdic tradicional tant de malaltia com de presa de decisions terapèutiques, els indicadors basats en la perspectiva del pacient estan més centrats —òbviament— en el pacient i encaixen molt millor amb una aproximació biopsicosocial al trastorn i un model de presa de decisions compartides amb relació al tractament. En segon lloc i estretament relacionat amb aquest primer punt, cal destacar l'escepticisme i les reticències/resistències de molts investigadors a l'hora de considerar indicadors basats en la perspectiva del pacient —no parlem ja de la incorporació de PUDVP com a membres de l'equip investigador (per exemple, Closson et al., 2016; Coupland et al., 2005)—, factors derivats en gran mesura d'una percepció esbiaixada i excloent de la PUDVP i la seva perspectiva (Heller, McCoy i Cunningham, 2004; Treloar i Holt, 2006), és a dir, d'una representació de les persones usuàries de drogues com a interlocutors no vàlids. Malgrat que hi ha diverses semblances i continuïtats entre els PRD i l'atenció centrada en el pacient (McNeil, Kerr, Pauly, Wood i Small, 2016; Trujols, Salazar et al., 1999), en l'àmbit més general del tractament de les addiccions hi ha una notable tradició «[...] that dismisses clients' perspectives as hopelessly distorted, irrational and out of touch with reality» (Miller i Miller, 2009, p. 685). En aquestes condicions, és poc probable que s'implementin metodologies realment participatives (Rose, 2009; Rose et al., 2011) a l'hora de desenvolupar noves MRCP. De la mateixa manera, és difícil que l'evidència basada en el pacient (Staniszewska et al., 2014) adquireixi el mateix estatus i reconeixement que l'evidència clínica i l'evidència econòmica o, en altres paraules, formi part integral de l'avaluació de resultats dels TMM o de qualsevol altra modalitat de tractament en l'àmbit de les addiccions. De fet, sembla que aquest estat d'injustícia epistèmica (Fricker, 2007) no només caracteritzaria l'avaluació dels tractaments esmentats (Rance i Treloar, 2015), sinó que també seria una situació força generalitzada en tot l'àmbit de l'atenció a la salut (Carel i Kidd, 2014; Kidd i Carel, en premsa).

En el rerefons d'aquest escenari hi batega també la qüestió de quines formes de coneixement i expertesa són definides com a legítimes i creïbles, és a dir l'atribució de diferents graus de legitimitat i credibilitat a diferents tipus/fonts d'evidència (Beresford, 2006). En termes més planers: què compta com a evidència? i qui decideix què compta? Com assenyala Goldenberg (2009, p. 170), «evidence is a social product, influenced by the variable power and authority held by different stakeholders (patients, medical researchers, hospital administrators, clinicians, policy makers, etc.) in producing and determining the parameters for what counts as evidence». No és estrany, doncs, tal com asseveren Williams i Glasby (2010), que fins ara s'hagi emfatitzat en excés una definició restrictiva del que constitueix evidència vàlida, una definició que privilegia unes aproximacions i veus particulars.

Abans de passar a l'apartat de conclusions, voldríem finalitzar la discussió intentant: *a*) acotar una definició del terme evidència basada en el pacient; *b*) destacar una de les principals condicions de possibilitat —més enllà de la disponibilitat de determinats instruments, tècniques i metodologies— per a la incorporació d'aquesta font d'evidència en l'avaluació de resultats dels TMM —o de qualsevol altra modalitat d'intervenció en el camp de les addiccions o, més genèricament, de l'atenció a la salut— i el seu procés de millora contínua; i *c*) emfatitzar algun dels principals canvis necessaris per possibilitar que l’evidència basada en el pacient adquireixi el mateix estatus i reconeixement que l’evidència clínica i l’evidència econòmica.

D’acord amb Staniszewska et al. (2014) i aplicant el terme a l’àmbit dels TMM, l’evidència basada en el pacient seria tota aquella informació que el pacient aporta sobre qualsevol aspecte del TMM o sobre la repercussió d’aquest tractament en l’experiència de viure amb un trastorn per consum d’opioides. Aquesta diversitat d’informacions pot incloure tant dades quantitatives com qualitatives —per a una discussió de les limitacions de fins i tot aquelles MRCP desenvolupades amb metodologies qualitatives i veritablement participatives, vegeu Neale i Strang (2015*a*, 2015*b*)— i són especialment rellevants a l’hora d’avaluar l’acceptabilitat, adequació i efectivitat del tractament (Staniszewska et al., 2010). En aquest sentit, l’evidència basada en el pacient —també anomenada *evidència basada en l’experiència en primera persona* (Duke i Thom, 2014), *evidència experiencial* (Williams i Glasby, 2010) o *evidència dels usuaris* (Beresford, 2005*b*)— possibilita disposar d’una nova perspectiva a l’hora de copsar/aprehendre com els pacients experimenten i veuen el tractament, i com hi responen.

Una de les principals condicions de possibilitat per assolir l’acceptació i el reconeixement de l’evidència basada en el pacient és la medicina —psicologia— basada en l’evidència (MBE). Contràriament a allò que semblaria esperable si focalitzem l’atenció en una de les seves aportacions més destacades i que ha acabat esdevenint el seu símbol més distintiu, és a dir, la piràmide o jerarquia dels nivells d’evidència, la MBE no només no ignora la perspectiva dels pacients sinó que considera els seus valors i preferències de forma explícita (per a una anàlisi detallada de determinades característiques de la MBE mateixa susceptibles però d’entorpir aquest procés, vegeu Greenhalgh, Snow, Ryan, Rees i Salisbury, 2015). Recordem, a tall d’exemple, les paraules d’un dels precursors de la MBE: «Evidence based medicine is not restricted to randomised trial and meta-analyses. […] Because it requires a bottom up approach that integrates the best external evidence with individual clinical expertise and *patients’ choice*, it cannot result in slavish, cookbook approaches to individual patient care» (Sackett, Rosenberg, Gray, Haynes i Richardson, 1996, p. 72, la cursiva és nostra). Així mateix, tal com assenyala Sacristán (2013), tot i que la MBE i la medicina centrada en el pacient poden semblar corrents antagòniques, es fa difícil entendre que una d’elles pugui assolir tot el seu potencial sense tenir l’altra com a referència contínua: «No debería practicarse una medicina centrada en el paciente que no estuviese basada en la mejor evidencia disponible, ni es posible imaginar una MBE cuyo objetivo final esté alejado del paciente individual» (Sacristán, 2013, p. 463).

Estretament relacionat amb aquest punt, cal destacar igualment que l'adequació o pertinència d'un determinat mètode/disseny de recerca hauria de jutjar-se prenent com a base la seva capacitat de donar resposta a la pregunta o a l'objectiu plantejat (Bédart i Ouimet, 2016). A banda, doncs, de les preguntes vinculades amb l'eficàcia i el cost-eficàcia de les intervencions, és palès que en els àmbits de l'atenció a la salut o dels serveis socials hi ha múltiples i molt diverses qüestions per a les quals els dissenys que ocupen posicions superiors en les classificacions tradicionals de jerarquies de recerca/evidència no estan especialment ben preparats.

Malgrat aquestes condicions, si no favorables almenys compatibles per al desenvolupament d'una avaluació de resultats que incorpori/valori diverses fonts d'evidència, cal emfatitzar que el ple reconeixement i l'òptim desenvolupament de l'evidència basada en el pacient requereix com a condició *sine qua non* un canvi substancial —i, molt probablement, de difícil i lenta implementació per tot el que comporta de trencament amb la tradició hegemònica de considerar els pacients com una mera font de dades i no com a veritables protagonistes del procés de recerca— en la manera d'avaluar els resultats d'una intervenció —i, per extensió, de fer recerca— en l'àmbit de l'atenció a la salut. No ens referim aquí als igualment necessaris avenços metodològics vinculats amb la síntesi i integració de diversos tipus d'evidència (Pearson et al., 2015; Pluye i Hong, 2014; Pope, Mays i Popay, 2007) o a la disponibilitat de noves tecnologies que facilitin la recollida/generació d'evidència basada en el pacient (per exemple, les comunitats digitals de pacients; Wicks, 2014; Wicks, Heywood i Heywood, 2013). Ens referim a la participació real i significativa dels pacients mateixos en les diferents fases del procés de recerca (Callard, Rose i Wykes, 2012; Hutchison, Rogers i Entwistle, en premsa; Sacristán et al., 2016).

No podem parlar d'incorporar les perspectives dels pacients sense incorporar els pacients mateixos a l'hora, per exemple, de decidir quines han de ser les principals variables de resultat objecte d'avaluació (Young i Bagley, 2016) o, fins i tot prèviament a això, en l'establiment de les prioritats de recerca en l'àmbit de les addiccions (Ferri, Davoli i D'Amico, 2013). Són necessaris, doncs, no només mecanismes, processos i aliances que possibilitin la incorporació i participació en igualtat de condicions dels pacients o usuaris —fet que els converteix en coinvestigadors—, sinó molt especialment el compromís dels investigadors «oficials» amb aquesta coinvestigació o coproducció de la recerca o de l'avaluació de resultats en salut. Tal com assenyala Bassi (2014, p. 75), «de lo que aquí se trata, verdaderamente, no es del sentido *light* contenido en el "dar voz" (también podría uno/a preguntarse, más importantemente, quiénes somos los/as académicos/as y/o investigadores/as para "dar voz", en nombre de qué o de quién la damos y con qué efectos). […] Se trata de la supresión del abismo entre "los/as que mandamos" y los/as que entran en la investigación del modo en que nosotros/as lo decidimos».

Únicament assumint/adoptant aquesta posició axiològica compromesa —és a dir, compartint equitablement poder/presa de decisions— serà possible una recerca que promogui plenament l'apoderament dels pacients (per a una anàlisi detallada dels vincles/engranatges entre apoderament, participació i centralitat del pacient, vegeu Castro, Van Regenmortel, Vanhaecht, Sermeus i Van Hecke, 2016) i possibiliti el desenvolupament de models i serveis d'atenció a la salut codissenyats i coproduïts entre tots els agents implicats, independentment de si en són proveïdors o usuaris (Ocloo i Matthews, 2016).

6.

Conclusions

En aquesta tesi s'han presentat i discutit diversos treballs que tenen com a denominador comú generar coneixement al voltant de —i amb— la perspectiva de la persona en TMM. D'acord amb els resultats dels treballs esmentats i amb relació als objectius i les hipòtesis plantejades a l'inici, s'exposen les conclusions finals següents:

Treball 1

a) L'avaluació realitzada pel clínic (psiquiatra i infermera) de la millora del pacient en TMM presenta una dèbil concordança amb la realitzada pel pacient mateix.

b) La millora percebuda pel pacient en TMM no està relacionada amb la seva satisfacció amb el tractament.

c) La millora percebuda pel pacient en TMM està dèbilment relacionada amb la seva opinió sobre la metadona com a fàrmac per al tractament de la dependència de l'heroïna.

Treball 2

d) Les puntuacions de la versió espanyola del TSQM, administrada a una mostra de pacients en TMM, presenten evidències d'una estructura factorial similar a l'obtinguda en l'estudi de desenvolupament de la versió original.

e) Les puntuacions de la versió espanyola del TSQM, administrada a una mostra de pacients en TMM, presenten evidències de consistència interna satisfactòries.

f) Les puntuacions de la versió espanyola del TSQM, administrada a una mostra de pacients en TMM, presenten evidències de validesa convergent satisfactòries.

Treball 3

g) Els pacients tractats en centres de més capacitat, que es perceben a si mateixos com a participants en certa manera actius a l’hora de prendre decisions relatives al tractament i que presenten un menor deteriorament pel que fa a funcionament psicosocial, es mostren més satisfets amb el TMM.

Treball 4

h) Els instruments de mesura de resultats comunicats pels pacients poden classificar-se, en funció del nivell de participació del pacient en el procés de disseny i desenvolupament de l’instrument, en les quatre categories següents: *a*) instruments generats pels pacients; *b*) instruments centrats en els pacients; *c*) instruments valorats pels pacients; i *d*) instruments irrellevants per als pacients.

Treball 5

i) Les enquestes de satisfacció dels pacients amb els TMM, tal com s’implementen en l’actualitat, no són una eina útil per a la millora de la qualitat assistencial.

Treball 6

j) Una avaluació de programes/resultats realment centrada en el pacient o usuari és necessària tant en l’àmbit de les intervencions de reducció de danys com en el cas dels tractaments dels trastorns addictius.

k) Una veritable participació del pacient o usuari en el procés de disseny i desenvolupament dels instruments de mesura implicats és un pas imprescindible amb vista a possibilitar una avaluació de resultats realment centrada en els pacients/usuaris.

l) Una avaluació de l'efectivitat de qualsevol intervenció o tractament en l'àmbit de les addiccions requereix un equilibri entre els instruments desenvolupats de manera habitual —és a dir, amb una participació limitada dels pacients— i les escales dissenyades amb metodologies veritablement participatives o, fins i tot, mitjançant estudis liderats pels pacients mateixos.

6.1. Noves línies de recerca

Els resultats i conclusions d'aquest tesi han suggerit la necessitat d'iniciar noves línies de treball, algunes de les quals ja estem desenvolupant actualment:

a) Fer una revisió sistemàtica que permeti identificar i descriure tots els instruments de mesura de la satisfacció amb els TMAO i classificar-los en funció: *a*) de la qualitat tant del seu procés de desenvolupament (utilitzant l'eina de valoració de la qualitat dels estudis sobre propietats dels instruments de mesura, desenvolupada per la iniciativa COSMIN [Mokkink et al., 2016; Terwee et al., 2012]) com de les pròpies característiques mètriques (segons els criteris de Terwee et al., 2007); *b*) de tipologies rellevants (per exemple, instruments dissenyats ad hoc i no validats *vs*. genèrics *vs*. específics; factuals *vs*. afectius; globals *vs*. multidimensionals); i *c*) del grau d'incorporació de la perspectiva del pacient en el seu procés de desenvolupament (seguint la tipologia proposada en el quart article d'aquesta tesi i la subdivisió dels instruments centrats en el pacient a partir de la classificació —consulta, contribució i col·laboració— proposada per Sweeney i Morgan [2009]).

b) Fer una revisió sistemàtica que permeti sintetitzar l'evidència existent sobre els nivells de satisfacció amb els TMAO i sobre les variacions d'aquests nivells de satisfacció en funció: *a*) dels agonistes opioides utilitzats en el tractament de manteniment; i *b*) dels tipus d'instruments implicats en l'avaluació de la satisfacció amb el tractament.

c) Desenvolupar un instrument d'avaluació de la satisfacció amb el TMM a partir de l'anàlisi qualitativa, mitjançant el procediment d'anàlisi de contingut categorial, de les dades textuals recollides/generades amb les dues preguntes obertes de tipus genèric —formulades amb relació a l'experiència amb el centre— pertanyents a la VSSS-MT («lo que más me ha gustado de mi experiencia con este centro de tratamiento con metadona es: …» i «lo que menos me ha gustado de mi experiencia con este centro de tratamiento con metadona es: …»), dades procedents dels tres primers estudis que componen aquesta tesi.

d) Desenvolupar, mitjançant metodologies qualitatives —i realment participatives— de recollida/generació i anàlisi de la informació, un instrument per avaluar el constructe de recuperació tal com el defineixen i l'operativitzen els pacients en TMM.

e) Desenvolupar, igualment amb la participació dels pacients i mitjançant metodologies qualitatives de recollida/generació i anàlisi de dades, noves MRCP per a l'avaluació de l'efectivitat i la qualitat de les intervencions en altres àmbits de l'atenció a la salut tan diferenciats com ara les intervencions d'infermeria en les unitats de cures intensives (Romero-García i Trujols-Albet, 2015) o el tractament de la depressió major (Trujols, Portella i Pérez, 2013).

f) Analitzar i mostrar les contradiccions que emergeixen quan es contraposen, d'una banda, la tradició de desestimar o, si més no, passar de puntetes sobre la perspectiva de la persona consumidora/dependent de substàncies psicoactives a l'hora d'avaluar l'efectivitat d'una intervenció o tractament concret, i de l'altra, la preponderància i la fiabilitat «atorgades» —implícitament i sense fer gaire soroll— a la perspectiva esmentada pels sistemes diagnòstics d'ús habitual en l'àmbit de les addicions —i pels instruments de cribratge i diagnòstics que s'hi basen. Per posar només un parell d'exemples —un més general, l'altre més concret— dels molts que podríem triar, podem assenyalar: *a*) que el diagnòstic de trastorn per consum d'opioides segons els criteris diagnòstics del DSM-5® (American Psychiatric Association, 2014) es basa essencialment en la informació proporcionada pel pacient mateix sobre la seva conducta, experiències i sensacions; i *b*) que el primer d'aquests criteris (consum freqüent en quantitats superiors o durant un temps més prolongat del previst) pressuposa/requereix «clarity about the difference between what one hoped or planned to do and what happened, between decisions in the past and actions in the present. It also assumes that present perceptions of past intentions accurately reflect those past intentions» (Fraser, Moore i Keane, 2014, p. 39).

7.

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