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REVIEW ARTICLE

Diversity or disarray? A systematic review of decision-making capacity for treatment and research in schizophrenia and other non-affective psychoses

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Background. Valid consent for treatment or research participation requires that an individual has decision-making capacity (DMC), which is the ability to make a specific decision. There is evidence that the psychopathology of schizophrenia can compromise DMC. The objective of this review was to examine the presence or absence of DMC in schizophrenia and the socio-demographic/psychopathological factors associated.

Methods. We searched three databases Embase, Ovid MEDLINE(R), and PsycINFO for studies reporting data on the proportion of DMC for treatment and research (DMC-T and DMC-R), and/or socio-demographic/psychopathological associations with ability to make such decisions, in people with schizophrenia and related illnesses.

Results. A total of 40 studies were identified. While high levels of heterogeneity limited direct comparison, meta-analysis of inpatient data showed that DMC-T was present in 48% of people. Insight was strongly associated with DMC-T. Neurocognitive deficits were strongly associated with lack of DMC-R and to a lesser extent DMC-T. With the exception of years of education, there was no evidence for an association with socio-demographic factors.

Conclusions. Insight and neurocognitive deficits are most closely associated with DMC in schizophrenia. The lack of an association with socio-demographic factors dispels common misperceptions regarding DMC and characteristics such as age. Although our results reveal a wide spectrum of DMC-T and DMC-R in schizophrenia, this could be partly due to the complexity of the DMC construct and the heterogeneity of existing studies. To facilitate systematic review research, there is a need for improvement within research study design and increased consistency of concepts and tools.

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Introduction

Consent for treatment or research requires the individual to have the ability to make a decision, known as decision-making capacity (DMC) (Grisso & Appelbaum, 1998). Many legislative regions now use DMC to regulate treatment or research participation (Appelbaum, 2007; Nicholson *et al.* 2008).

Non-affective psychotic illnesses such as schizophrenia and its symptoms can compromise DMC (Appelbaum & Grisso, 1995; Grisso & Appelbaum, 1995; Grisso *et al.* 1995). Assessments of DMC for treatment (DMC-T) can result in substantial changes in a person's experience of treatment: either autonomous decision making for oneself or decisions made by others. In decisions regarding research participation lacking DMC for research (DMC-R), or being deemed likely to lack it, may lead to ineligibility for research recruitment.

Given that DMC is decision-specific, the information to be understood is different for each decision (Jacob *et al.* 2013). Therefore, the same individual may lack DMC for one decision but not another (Grisso & Appelbaum, 1998). Furthermore, DMC also involves considering this information within the context of personal circumstances, beliefs, and values. Understanding lack of DMC in people with schizophrenia, the associated symptoms, to what extent loss is decision-specific and how individual context might effect DMC is of critical importance to all clinicians working with this mental disorder.

DMC is a complex construct. The underlying abilities, e.g. understanding or reasoning, can be measured as dimensional or categorical (such as by applying a cut-off). In clinical and legal practice a decision must

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be made that the person has, or lacks, the ability for DMC, making it a binary judgement.

Different legislative regions have separate legal definitions for the abilities which are jointly necessary for DMC. In England and Wales the legal test is defined by the Mental Capacity Act 2005 (MCA) and requires the ability to: 'understand' the information relevant to a decision; 'retain' it; 'use or weigh' the information to arrive at a decision; and 'communicate' that decision. Many US states use a similar model – the 'four factor model' of 'understanding', 'appreciation', 'reasoning', and 'expressing a choice' (Appelbaum & Grisso, 1995; Grisso & Appelbaum, 1995; Grisso *et al.* 1995). The four factors of the MCA are viewed as largely synonymous with the US four factors, with 'use or weigh' incorporating 'appreciation' and 'reasoning' (Owen *et al.* 2009*a*). Assessments of DMC for legal and medical consent are made by clinicians or the court based on the relevant legal test. Such assessments are, ultimately, the 'gold standard' of DMC assessment and, although the court is the final arbitrator, the assessment process itself is delegated mainly to clinicians.

Research into DMC has therefore measured DMC in one of three ways:

(1) 'Dimensional scores': use of structured tools to psychometrically assess performance within individual domains of abilities deemed core to DMC (such as the 'four factor model') to return a score for each dimension.
(2) 'Cut-off standard': applying a cut-off or scoring algorithm to 'dimensional scores'.
(3) 'Judgement standard': clinical or court assessment of DMC returning a binary judgement. This may or may not be guided by legal criteria and dimensions to be assessed (such as the MCA in the UK or the 'four factor model' in the USA).

Each approach has both advantages and limitations: The 'cut-off standard' and 'dimensional scores' are primarily for research use, and allow for a more detailed exploration of symptoms contributing to DMC vulnerability than the 'judgement standard' permits. The 'judgement standard' is *the* standard of DMC in clinical and legal practice, although it may be guided by the other two tools. A highly influential study, the MacArthur Treatment Competence study (Appelbaum & Grisso, 1995; Grisso & Appelbaum, 1995; Grisso *et al.* 1995), developed a set of tools for assessing DMC-T using 'dimensional scores' based on the 'four factor model'. These were subsequently condensed into the MacArthur Competence Assessment Tool for Treatment (MacCAT-T) (Grisso *et al.* 1997) and then adapted for decisions regarding Clinical Research (MacCAT-CR) (Appelbaum & Grisso, 2001). These tools led to an explosion of research into DMC, with many studies measuring DMC using 'dimensional scores'.

The objective of the present review was to explore proportions and clinical associations of DMC in people with schizophrenia using these three standards (for the purpose of clarity we use the term 'schizophrenia' to refer to non-affective psychosis including, but not limited to, schizoaffective disorder, delusional disorder, transient psychotic episodes etc.). Our research questions were:

(1) What proportion of people with schizohrenia has DMC for specified civil decisions (such as treatment or participation in research) in specified settings (e.g. inpatient, outpatient)?
(2) What are the associations with DMC for civil decisions? We pre-specified associations of interest as positive symptoms, negative symptoms, general symptoms of psychosis, neurocognitive symptoms, affective symptoms, awareness of illness (insight) and socio-demographic variables (age, sex, ethnicity and educational level).

To our knowledge there have been two previous systematic reviews into DMC in schizophrenia, rather than in conjunction with other diagnoses such as dementia or bipolar affective disorder (Jeste *et al.* 2006; Wang *et al.* 2016). However, unlike ours, both these reviews focused primarily on a comparing dimensional DMC scores in those diagnosed with schizophrenia and in 'normal controls', finding that people with schizophrenia did less well.

Methods

Eligibility criteria

We included studies published in English, which assessed the DMC of samples of people over the age of 18 diagnosed with non-affective psychosis, as defined by: f20-29 ICD-10 (World Health Organization., 1993) or 295, 297, 298 DSM-IV (American Psychiatric Association., 1994). We included studies measuring DMC or domains of DMC using the three approaches described above: the 'judgement standard'; 'cut-off standard'; or 'dimensional scores'. We excluded non-civil assessments of DMC (such as fitness to plead).

Search

We used OVID to search Embase, Ovid MEDLINE (R), and PsycINFO. Our search string was chosen following several trial iterations of searches to maximise the sensitivity of the search, given that 'capacity' has multiple homonyms. Our final search string was a title and

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abstract search of: (capacity or competence or competency or 'decision making' or 'decision-making') AND (schizophrenia or psychosis or 'mental illness' or 'mental disorder' or psychotic). The search was completed on 16 February 2015, with results exported to Endnote X7. The citation search was performed on 17 July 2015, with all steps in both searches performed by B Spencer (BS).

References reporting data from the same study were excluded unless the samples were mutually exclusive. Exclusion occurred at the data extraction stage and following correspondence with the authors. In these cases the reference best suited to the review was selected by BS for retention within the final selection. In addition, if multiple references reported complementary analyses of the same sample they were treated as one reference in the final analysis.

Data collection and data items

BS extracted all data using a data extraction form which specified: population studied and associated demographics; nature of decision for which DMC was assessed (whether it was for a decision related to the present disorder, such as treatment for schizophrenia rather than treatment for another unrelated medical condition, and, in the case of DMC-R, whether it was for hypothetical or real study involvement); outcome of the DMC assessment (proportions from studies using 'judgement standard' and 'cut-off standard'); effect sizes (ES) for any associations between DMC and variables of interest. Only summary data, rather than data on individual items of tools were extracted from studies. The only exception was item G12 on the Positive and Negative Syndrome Scale (PANSS) (Kay *et al.* 1987) 'lack of judgement and insight', which we chose to include, given that this was the primary measure of insight used in several studies.

Statistical analysis

Confidence intervals (95%) were calculated for proportions of DMC following 'judgement standard' or 'cut-off standard' using the Wilson score interval. Odds ratios and correlation coefficients were converted into ES for our principal summary measure. Given that some studies were able to detect very small ES, we modified the Cohen criteria (Cohen, 1992) to: >0 to $\leqslant$0.3 small ES, $\geqslant$0.3 medium ES, and $\geqslant$0.5 large ES.

We aimed to meta-analyse the proportions of people with DMC as measured by the 'judgement standard'. For studies to be eligible for the meta-analysis for DMC, they needed to test DMC for similar decisions (e.g. DMC-T for treatment of the present disorder) within a homogenous setting (e.g. solely inpatients or outpatients) and without other factors likely to bias the result as decided by the authors (e.g. not systematically excluding detained or severely unwell people). Meta-analysis of proportions was performed using STATA 14 (StataCorp). Given the residual heterogeneity between studies, a random effects model was used.

Risk of bias assessment

To our knowledge there has been no prior attempt to appraise quality in DMC studies. We considered certain factors to be important based on our clinical experience when reviewing studies on DMC. These included: (1) the exact nature of the decision for which DMC is being assessed (whether it was real, hypothetical, related to the present disorder – schizophrenia or wholly unrelated), as this may impact on effect of symptoms of schizophrenia on DMC (for example, whether insight into illness is relevant to the decision, whether the decision was cognitively demanding, etc.); (2) homogenous setting of recruitment (either all inpatients or outpatients and thus controlling for hidden confounders in these settings); (3) ability to recruit people with a range of severity of illness within a specified setting, given that this would likely impact on DMC (e.g. were people deemed to be 'too unwell' systematically excluded from the sample). We developed a risk of bias assessment based on these which demonstrated critical risk of bias for the majority of studies (available from the authors on request). As we wanted to provide an overview of the literature, we decided to exclude a risk of bias assessment from this review, but comment further on the quality of research in the discussion.

Results

Of 11 658 references screened from titles, 682 references went to full text review, and 40 met our inclusion criteria (see Fig. 1) (Weinstock *et al.* 1984; Veliz & James, 1987; Norko *et al.* 1990; Bean *et al.* 1994; Appelbaum & Grisso, 1995; Grisso & Appelbaum, 1995; Grisso *et al.* 1995, 1997; Carpenter *et al.* 2000; Moser *et al.* 2002, 2005, 2006; Valletto *et al.* 2002; Wong *et al.* 2000, 2005; Bellhouse *et al.* 2003; Kovnick *et al.* 2003; Vollmann *et al.* 2003; Cohen *et al.* 2004; Palmer *et al.* 2004, 2005; Srebnik *et al.* 2004; Cairns *et al.* 2005; Eyler *et al.* 2005, 2007; Koren *et al.* 2005; Stroup *et al.* 2005; Candilis *et al.* 2006, 2008; Palmer & Jeste, 2006; Dunn *et al.* 2007; Moye *et al.* 2008; Kavanagh *et al.* 2008; Jeste *et al.* 2009; Owen *et al.* 2009*a*, 2011; De Marco *et al.* 2010; Capdevielle *et al.* 2009; Linder *et al.* 2012; Di & Cheng, 2013; Fischer *et al.* 2013; Kumar *et al.* 2013; Lan *et al.* 2013; Raffard *et al.* 2013; Skipworth *et al.* 2013; Chiu *et al.* 2014). A

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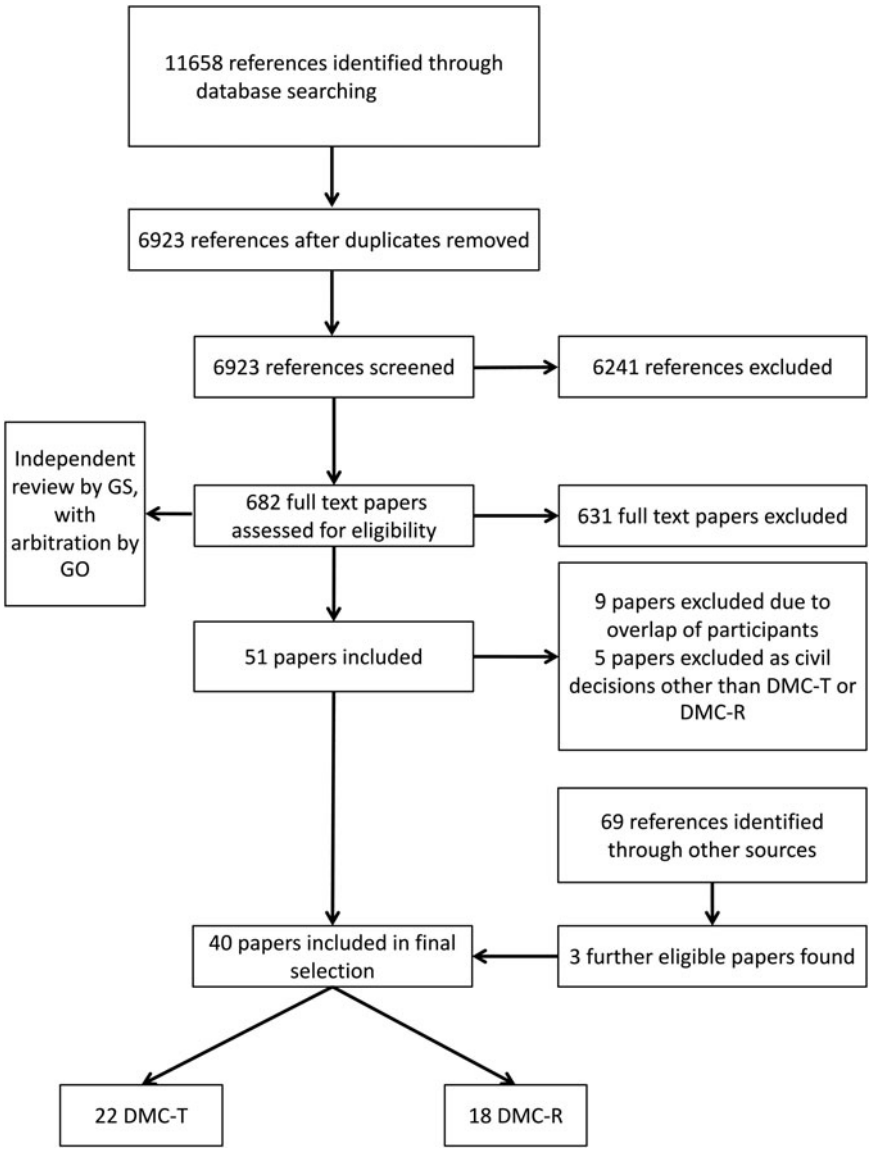

Fig. 1. Flow diagram.

clinician with expertise in the field [G Shields (GS)] performed an independent review of all 682 references applying the inclusion and exclusion criteria. Inter-rater reliability between BS and GS was high ($K = 0.80$). Disagreements were resolved following discussion between BS and GS, while any unresolved disputes went to G Owen (GO) as final arbiter ($n = 3$).

Heterogeneity between studies was high, with considerable variation in study design, population, measurements and the nature of decision for which DMC was assessed (see Table 1). Many studies reported only partial data for the outcomes of interest, while the studies assessing DMC using a 'judgement standard' rarely presented any associations with our prespecified variables of interest. Results from all studies and characteristics are available in the online supplemental data table. Most studies assessed psychopathology using either the PANSS or Brief Psychiatric Rating Scale (BPRS) (Overall & Gorham, 1962). Many studies used a range of diverse individual neurocognitive sub-tests from various test batteries (such as the Wechsler Adult Intelligence Scale – III [WAIS-III (Wechsler, 1997)] without a summary score provided. These individual results were not extracted, given the difficulties in direct comparison between studies.

Given the limited numbers of studies investigating decisions other than DMC-T and DMC-R ($n = 5$), we limited our review to treatment and research ($n = 40$). These five studies considered DMC for organ donation (De Marco *et al.* 2010), making a psychiatric advance directive (Valletto *et al.* 2002; Srebnik *et al.* 2004;

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Table 1. *Main characteristics of studies*

DMC-T or DMC-R	Standard used	Decision related to schizophrenia	Population setting	Decision to be made by participant	Format of assessment	Associations reported	Other features	Title
DMC-T	Expert judgement	Related	Mixed	Current psychiatric treatment with medication	Clinical assessment under the criteria of the MCA 2005 and structured using the MacCAT-T		Mixed inpatients and outpatients under forensic services	Skipworth *et al.* (2013)
			Inpatients	Treatment in hospital with ECT	Clinical assessment (no further details)		Inpatients requiring ECT	Bean *et al.* (1994)
					Clinical assessment (no further details)		Patients who received ECT without consent	Chiu *et al.* (2014)
				Current psychiatric treatment	Clinical assessment (no further details)		Referred to the Court for determination of lack of competency to refuse or consent to treatment forensic population	Veliz & James (1987)
				Current admission and psychiatric treatment	Clinical assessment under the criteria of the legal precursor to the MCA and structured according to this			Bellhouse *et al.* (2003)
				Current psychiatric treatment with medication	Clinical assessment under the criteria of the legal precursor to the MCA and structured and structured using the MacCAT-T			Cairns *et al.* (2005)
				Either current admission or psychiatric treatment in hospital	Clinical assessment under the criteria of the MCA and structured using the MacCAT-T	SAI, BPRS		Owen *et al.* (2009*a*, 2011)
		Unrelated	N/A	Physical health treatment in a medical hospital	Clinical assessment using criteria based on early precursors to the four factor model, unstructured		Medically unwell in a physical health hospital referred for determination of DMC-T for medical treatment.	Weinstock *et al.* (1984)
		Unclear	Mixed	Routine blood test	Clinical assessment under the criteria of the legal precursor to the MCA and structured according to this		Decision for a blood test – unclear degree related.	Wong *et al.* (2000)

Cut-off	Related	Inpatients	Current psychiatric treatment	SSICA	Socio-demographics	Guardian also needed to agree in order to participate in study.	Di & Cheng (2013)
			Current admission and psychiatric treatment	Tool assessing early precursors to the four factor model		No detained patients	Norko *et al.* (1990)
	Unrelated	Outpatients	Hypothetical medical vignette involving a toe amputation or femoral bypass in non-healing toe ulcer	ACCT		⩾60 years old	Moye *et al.* (2008)
Four factor scores	Related	Outpatients	Current psychiatric treatment with atypical antipsychotic medication	MacCAT-T	PANSS, BPRS, DRS, socio-demographics.	Outpatients, although most living at community assisted living facilities. ⩾40 years old	Palmer *et al.* (2004)
			Current psychiatric treatment	MacCAT-T.	SUMD, PANSS, BDI, socio-demographics	No treatment changes for the past month	Capdevielle (2009)
			Current psychiatric treatment with antipsychotic medication	MacCAT-T	PANSS, BDI, socio-demographics	No treatment changes for the past month	Raffard *et al.* (2013)
		Inpatients	Current psychiatric treatment	MacCAT-T precursors	BPRS, VCF, socio-demographics	Clinicians requested really unwell people to not be recruited.	Appelbaum & Grisso (1995); Grisso & Appelbaum (1995); Grisso *et al.* (1995)
				MacCAT-T.	BRPS, socio-demographics		Grisso *et al.* (1997)
				MacCAT-T		Within 2 weeks of admission when clinician has determined them able to cooperate	Koren *et al.* (2005)
			Maintenance antipsychotic treatment following discharge from hospital	MacCAT-T	G12 PANSS insight, PANSS, MADRS, socio-demographics	Before discharge from hospital	Wong *et al.* (2005)
Cut-off and expert judgement	Related	Inpatients	Current psychiatric treatment with medication	Clinical assessment under the criteria of the four factor model, unstructured, MacCAT-T	Socio-demographics	No detained patients	Vollmann *et al.* (2003)

Table 1 (*cont.*)

DMC-T or DMC-R	Standard used	Decision related to schizophrenia	Population setting	Decision to be made by participant	Format of assessment	Associations reported	Other features	Title
DMC-R	Cut-off	Related	Outpatients	RCT of adjunctive therapy to usual antipsychotic regimen	mESC	BPRS, MMSE	Already recruited to the parent study (deemed to have DMC-R)	Fischer *et al.* (2013)
			Mixed	RCT of atypical antipsychotic medication	MacCAT-CR	BIQ, PANSS, HAM-D, neurocognitive Z score, DRS, socio-demographics	Mixed outpatient and inpatients, including board and care homes. Aged ⩾50	Dunn *et al.* (2007)
	Four factor scores	Related	Outpatients	fMRI study of decision-making capacity	MacCAT-CR		Outpatient study recruiting from board and care homes	Eyler *et al.* (2005)
			Mixed	RCT of antipsychotic medication	MacCAT-CR	BPRS, RBANS		Carpenter *et al.* (2000)
				CATIE study (naturalistic antipsychotic treatment study)	MacCAT-CR	PANSS, neurocognitive Z score, socio-demographics	Mixed inpatients and outpatients already recruited to the CATIE study (having suboptimal antipsychotic treatment) and passing a MacCAT-CR based DMC-R threshold (U ⩾ 16)	Stroup *et al.* (2005)
				Observational study of tardive dyskinesia and other side effects of atypical antipsychotic medications	MacCAT-CR	BIQ, PANSS, HAM-D, neurocognitive Z score, socio-demographics	Mixed inpatients and outpatients, some in board and care homes. Aged ⩾40	Palmer & Jeste (2006)
			Inpatients	RCT of antipsychotic medication	MacCAT-CR	BPRS, VCF	Long stay patients on a research ward with schizophrenia.	Kovnick *et al.* (2003)
		Unclear	Outpatients	RCT of cognitive enhancement medication	MacCAT-CR	PANSS, MMSE, socio-demographics	Aged ⩾60	Palmer *et al.* (2005)
					MacCAT-CR		Recruited before medication free period as an inpatient for treatment of schizophrenia. Only data on correlations are the effect of interventions	Moser *et al.* (2005)
					MacCAT-CR		Only data on correlations are the effect of interventions	Moser *et al.* (2006)

			fMRI study of decision-making capacity	MacCAT-CR	PANSS, socio-demographics	Outpatient study recruiting from board and care homes	Eyler *et al.* (2007)
	Mixed	RCT of cognitive	enhancement medication	MacCAT-CR, ESC	RBANS		Moser *et al.* (2002)
	Inpatients	RCT of cognitive	enhancement medication	MacCAT-CR, Clinical assessment of audio-tapes of MacCAT-CR but no absolute scores reported	G12 PANSS insight, PANSS, CGI, MMSE	Members of a hospital-based therapeutic community. Stable patients	Lan *et al.* (2013)
	Unrelated	Mixed	RCT for an antibiotic for sore throat *v.* an established treatment.	MacCAT-CR	PANSS, MMSE, socio-demographics		Candilis *et al.* (2006, 2008)
	Two studies one related one not	Inpatients	Two studies: (1) RCT of antipsychotic medication; (2) Ketamine PET scan study	MacCAT-CR			Cohen *et al.* (2004)
	Not reported	Inpatients	Hypothetical clinical trial – no further information	Clinical assessment (no further details or absolute scores reported), MacCAT-CR	FAB, ACE	Voluntary inpatients admitted for >6 months	Linder *et al.* (2012)
Four factor scores and expert judgement	Unclear	Outpatients	RCT of cognitive enhancement medication	MacCAT-CR, clinical assessment based on reviewing the MacCAT-CR records using the criteria of the four factor model	PANSS, HAM-D, RBANS, socio-demographics	Outpatients aged >40	Jeste *et al.* (2009)

Legend: ACCT, Assessment of Capacity to Consent to Treatment Interview, ACE, Addenbrooke's Cognitive Exam, BDI, Beck Depression Inventory, BIQ, Birchwood Insight Questionnaire, BPRS, Brief Psychiatric Rating Scale, CGI, Clinical Global Impression, DRS, Mattis Dementia Rating Scale, ESC, Evaluation to Sign Consent, FAB, Frontal Assessment Battery, HAM-D, Hamilton Depression Rating Scale, MacCAT-CR, MacArthur Competence Assessment Tool for Clinical Research, MacCAT-T, MacArthur Competence Assessment Tool for Treatment, MADRS, Montgomery-Åsberg Depression Rating Scale, mESC, Modified Evaluation to Sign Consent, MMSE, Mini-Mental State Exam, PANSS, Positive and Negative Syndrome Scale, RBANS, Repeatable Battery for the Assessment of Neuropsychological Status, SAI, Schedule for the Assessment of Insight, SSICA, Semi-structured inventory for competence assessment, SUMD, Scale to assess Unawareness of Mental Disorder, VCF, Verbal Cognitive Functioning.

NB – many studies also reported on individual neurocognitive sub-tests from various test batteries, these are not presented in this table.

Kumar *et al.* 2013), and DMC to manage one's own finances (Barrett *et al.* 2009).

Performance on different standards of DMC

Proportion of DMC-T in studies using 'judgement standard' and 'cut-off standard'

Ten studies reported the proportion of DMC-T amongst participants when using the 'judgement standard' (Weinstock *et al.* 1984; Veliz & James, 1987; Bean *et al.* 1994; Wong *et al.* 2000; Bellhouse *et al.* 2003; Vollmann *et al.* 2003; Cairns *et al.* 2005; Owen *et al.* 2009*a*, 2011; Skipworth *et al.* 2013; Chiu *et al.* 2014), while three studies used the 'cut-off standard' (Norko *et al.* 1990; Moye *et al.* 2008; Di & Cheng, 2013). Characteristics and results from all studies providing data on 'judgement standard' or 'cut-off standard' of assessment are presented in Table 2 (Chiu *et al.* 2014 and Norko *et al.* 1990 are excluded and considered separately below). The range of proportions of DMC-T reported by all studies is large (11–100%) and there is significant heterogeneity between studies: six studies recruited from inpatient settings (Veliz & James, 1987; Bean *et al.* 1994; Bellhouse *et al.* 2003; Vollmann *et al.* 2003; Cairns *et al.* 2005; Owen *et al.* 2009*a*, 2011; Di & Cheng, 2013), one from outpatients (Moye *et al.* 2008), two from mixed inpatients and outpatient settings (Wong *et al.* 2000; Skipworth *et al.* 2013), and one from a general medical hospital setting (Weinstock *et al.* 1984). Seven studies assessed DMC-T for a decision that was related to the disorder (hospital admission or treatment for schizophrenia) (Veliz & James, 1987; Bean *et al.* 1994; Bellhouse *et al.* 2003; Vollmann *et al.* 2003; Cairns *et al.* 2005; Owen *et al.* 2009*a*, 2011; Di & Cheng, 2013; Skipworth *et al.* 2013); two assessed DMC-T for medical treatment unrelated to schizophrenia (Weinstock *et al.* 1984; Moye *et al.* 2008); and one assessed DMC-T for treatment with an unclear relationship to schizophrenia (Wong *et al.* 2000). Two studies assessed DMC-T as a naturalistic study in which people were recruited following concerns regarding a lack of DMC-T having been raised (Weinstock *et al.* 1984; Veliz & James, 1987).

It was only within the set of studies recruiting from inpatient settings that there were two or more studies sufficiently comparable with each other in terms of recruitment setting and nature of decision for which DMC-T was assessed in order to be eligible to undergo meta-analysis (Bean *et al.* 1994; Bellhouse *et al.* 2003; Cairns *et al.* 2005; Owen *et al.* 2009*a*, 2011; Di & Cheng, 2013). These studies assessed DMC-T for psychiatric admission and/or treatment in hospital with medication or ECT; three were UK-based and used the MCA legal standard. The range of people with DMC-T was 26–67%. A meta-analysis of proportions using a random effects model indicated high heterogeneity (I^2 – 84.41%) and a pooled proportion of 48% (95% CI 29–66%) with DMC-T (see Fig. 2).

Of the two studies considered separately: Norko *et al.* (1990), used a range of 'cut-offs' based on combinations of 'dimensional scores', and found that DMC varied between 45% and 80%, depending on the precise cut-off used. Chiu *et al.* (2014) reported the characteristics of people given Electro-Convulsive Therapy (ECT) without consent, dichotomising the groups into people without DMC-T given ECT and people with DMC-T given ECT despite objecting. In those having ECT without consent, $n = 13$, 76% (95% CI 53–90%) lacked DMC-T.

Proportion of DMC-R from 'judgement standard' and 'cut-off standard'

One study (Dunn *et al.* 2007) tested DMC-R concerning a hypothetical decision related to schizophrenia in a mixed population of inpatients and outpatients. It used three 'cut-off standards', 'least'; 'intermediate'; and 'most', (the 'Dunn standard') and found that 92, 81, 43% met their standards for each of these, respectively. Another study used a 'judgement standard' to test DMC-R amongst older outpatients (Jeste *et al.* 2009) and found that 47% of those undergoing 'routine consent' had DMC-R.

'Dimensional scores' and DMC-T/DMC-R

Five studies reported 'dimensional scores' from MacCAT-T sub-scales (Grisso *et al.* 1997; Palmer *et al.* 2004; Koren *et al.* 2005; Wong *et al.* 2005; Capdevielle *et al.* 2009), and thirteen studies reported 'dimensional scores' from MacCAT-CR sub-scales (Carpenter *et al.* 2000; Moser *et al.* 2002, 2005, 2006; Kovnick *et al.* 2003; Palmer *et al.* 2005; Stroup *et al.* 2005; Candilis *et al.* 2006; Palmer & Jeste, 2006; Dunn *et al.* 2007; Eyler *et al.* 2007; Candilis *et al.* 2008; Jeste *et al.* 2009; Lan *et al.* 2013). These were all reported as arithmetic means and standard deviations. One study provided 'dimensional scores' from the precursor tools to the MacCATs (Appelbaum & Grisso, 1995; Grisso & Appelbaum, 1995; Grisso *et al.* 1995). Given that the data are consistently reported as highly skewed, a formal statistical comparison between the studies cannot be made, while study heterogeneity already renders comparison of questionable usefulness.

Associations

Most associations were reported as correlations with 'dimensional scores' based on the 'four factor model'. These are summarised and presented along with associations with the 'judgement standard' in Table 3.

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Table 2. *Summary of DMC-T studies with a binary outcome of DMC-T*

Study	DMC standard	Decision assessed	Setting	Other relevant features	Total study *N*	*n* with DMC-T	Proportion with DMC-T (95% CI)
Weinstock *et al.* (1984)	Clinical	Unrelated medical treatment	N/A	Medically unwell in a physical health hospital referred for determination of DMC-T for medical treatment	*N* = 2	*n* = 2	1 (0.34–1)
Veliz & James (1987)	Clinical	Related psychiatric treatment	Inpatients	Referred to the Court for determination of lack of competency to refuse or consent to treatment forensic population	*N* = 35	*n* = 4	0.11 (0.05–0.26)
Bean *et al.* (1994)	Clinical	Related psychiatric treatment	Inpatients	Inpatients requiring ECT	*N* = 32	*n* = 19	0.59 (0.42–0.75)
Wong *et al.* (2000)	Clinical	Blood test – unclear degree related	Mixed		*N* = 21	*n* = 19	0.90 (0.71–0.97)
Bellhouse *et al.* (2003)	Clinical	Related psychiatric treatment	Inpatients		*N* = 9	*n* = 6	0.67 (0.35–0.88)
Vollmann *et al.* (2003)	Clinical	Related psychiatric treatment	Inpatients	No detained patients.	*N* = 43	*n* = 35	0.81 (0.67–0.90)
Moye *et al.* (2008)	Threshold	Unrelated medical treatment	Outpatients	>60 years old	*N* = 20	*n* = 4	0.2 (0.08–0.42)
Cairns *et al.* (2005)	Clinical	Related psychiatric treatment	Inpatients		*N* = 62	*n* = 30	0.48 (0.36–0.61)
Owen *et al.* (2009*a*, 2011)	Clinical	Related psychiatric treatment	Inpatients		*N* = 93	*n* = 24	0.26 (0.18–0.36)
Di & Cheng (2013)	Threshold	Related psychiatric treatment	Inpatients	Guardian also needed to agree in order to participate in study.	*N* = 192	*n* = 138	0.72 (0.65–0.78)
Skipworth *et al.* (2013)	Clinical	Related psychiatric treatment	Mixed	Mixed inpatients and outpatients under forensic services	*N* = 97	*n* = 63	0.65 (0.55–0.74)

Associations with DMC-T

With the exception of insight, neurocognition, and socio-economic status (which includes a measure of years of education) most studies found no associations with DMC-T measured using either 'dimensional scores' or the 'judgement standard'. There was no heterogeneity between direction of associations when they were found by studies.

There was strong evidence for a negative association between lack of insight and DMC-T (medium to large ES), and positive association between better neurocognitive performance and DMC-T (medium ES). These associations covered a range of different dimensions with no discernible pattern for individual abilities such as 'understanding'.

The lack of any association with most socio-demographic variables (age, gender, race) is notable. There was a positive association in one study with higher socio-economic status and DMC-T, and weak evidence for a positive association for more years of education and DMC-T, especially with 'Understanding' (small to large ES).

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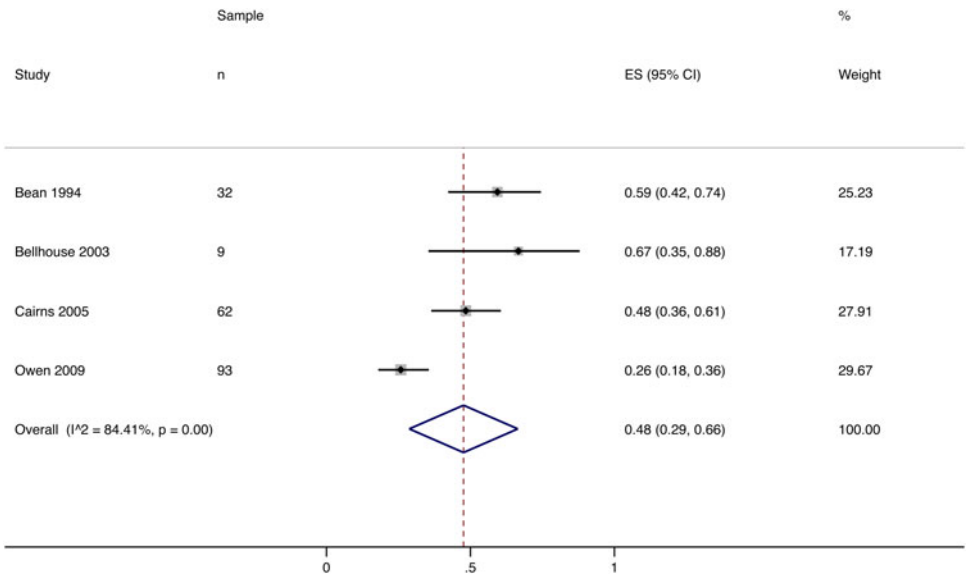

Fig. 2. Meta-analysis of proportions of patients with DMC-T.

With regards to symptoms of psychosis and DMC-T, there was some evidence for a negative association of PANSS total symptoms and PANSS negative symptoms with 'understanding' (medium to large ES). There was little evidence for a possible negative association of PANSS positive and PANSS general symptoms with dimension scores; overall, the majority of studies did not find any associations. One study reported on associations with BPRS factors. These are not included in the summary table (Appelbaum & Grisso, 1995; Grisso & Appelbaum, 1995; Grisso *et al.* 1995) but are in the online supplemental data table, and did not differ from the general pattern of the findings of associations of psychotic symptoms with DMC-T. No associations were found with affective symptoms.

Associations with DMC-R

The associations with DMC-R were similar to DMC-T with a few notable exceptions. Again, there was no heterogeneity between direction of associations when they were found by studies. As with DMC-T, other than one multi-centre study (Stroup *et al.* 2005), which reported negative associations between DMC-R and both 'non-white' ethnicity (small ES) and age and 'reasoning' (small ES), all studies found no associations with socio-demographics and DMC-R. Again there was weak evidence for a positive association for more years of education and DMC-R (small to large ES).

There was evidence for a positive association of better neurocognitive performance and DMC-R, which was much stronger than for DMC-T (small to large ES). By contrast, the associations with insight and DMC-R were fewer and of smaller ES than with DMC-T (small to medium ES).

There was a range of negative associations with DMC-R and measures of psychotic symptoms (PANSS scores and BPRS – small to large ES), which appears stronger than with DMC-T, and perhaps not as specific to 'understanding'. Unlike DMC-T, there was also evidence for a negative association between PANSS general and PANSS negative symptoms with dimension scores. Two studies reported on associations with BPRS factors (again not included in the summary table but are included in the online supplemental data table) (Carpenter *et al.* 2000; Kovnick *et al.* 2003). These results did not substantially differ from the general pattern of the findings of associations of psychotic symptoms with DMC-R.

Discussion

DMC-T v. *DMC-R in schizophrenia*

Following meta-analysis, DMC-T, when measured by the 'judgement standard' was present in 48% of people receiving inpatient treatment for schizophrenia. The range of the proportion with DMC-T was wide (26–67%). Heterogeneity between both samples and different decisions for which DMC was assessed was high. Outside of the analysis of DMC-T restricted to inpatient populations, it is difficult to draw any other distinct conclusions, using either 'judgement standards' or 'cut-off standards', beyond the finding that there is a wide range of DMC-T and DMC-R proportions in different samples of people with schizophrenia.

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Table 3. *Associations with DMC-T and DMC-R Associations with DMC-T in red, DMC-R in black*

	Associated with lack of DMC/worse performance on dimension scores				Associated with presence of DMC/better performance on dimension scores		
Effect size (cohen's d)	L	M	S	No association	S	M	L
	⩾0.5	<0.5	<0.3	0	<0.3	<0.5	⩾0.5
Lack of insight	P A R	U A R C P[a]	U A R	U U A R CC			
PANSS Total	UU	U A R UU A	R	AA RR CC U A R CC			
PANSS General	U U A R	U A C	UU A R C	U AA RR CC P[a] UU A RR C			
PANSS +VE		U A R	U A	UUU AAAA RRRR CCC P[a] UUUUUU AAA RRRR CCCC			
PANSS –VE	U U A	UU U A R	UU A R C	U AAAA RRRR CCC P[a] UUU AA RRR CCC			
BPRS	 U A	P U R		UU AAA RRR CC P U A R C			
Affective symptoms				UUU AAA RRR CC P[a] UU A R C			
Higher neurocognitive performance				AA P AA RRRR CCCCC	U A RR	UU RR C P[b]P[a] UUU AA	UUUUU AAA RR
Older age			R	PP UUUUU AAAAA RRRRR CCCC P[a] UUUUUU AAAA RRR CCC			
Male gender				PP UU AA RR CC UUU AA RR C			
Black and minority ethnicity			A R	UU AA RR CC UU A R C			
Higher socio-economic status				A	R	U	
More years of education				P UU AAAAA RRRR CCCC P[a] UUU A RR CCC	R U A RR	UU UA	P U A

Each letters symbolises an individual study finding an association, with horizontal position on the table representing direction of association and effect size. Individual letters represent the DMC standard the association was found with: P, association with binary outcome of DMC; U, association with 'understanding'; A, association with 'appreciation'; R, association with 'reasoning'; C, association with 'expressing a choice'.

[a] Dunn *et al.* (2007) used three standards as their binary outcome so the 'most' standard was selected as this required scoring in 'understanding', 'appreciation', and 'reasoning', rather than the other two standards, which just required scores in 'understanding'. Dunn also used two presented data on two summary summary neurocognitive scores (DRS and a neurocognitive z score), the neurocognitive z score is presented here.

[b] Linder *et al.* (2012) presented data on two summary neurocognitive scores (FAB positive association of medium ES, ACE no association), the FAB score is reported here.

There was little evidence that socio-demographic factors had an impact on DMC-T or DMC-R. The lack of association between DMC and basic demographics is both a reassuring and an important finding, given that DMC measurement outcomes should not, in principle, be influenced by age, gender, or ethnicity. It runs counter to common misconceptions or presumptions that might be made regarding a lack of DMC with certain demographic characteristics such as age. Nevertheless, there was some weak evidence of an association with greater years of education.

While there was strong evidence of an association between greater insight and DMC-T, evidence of a similar association with DMC-R was much weaker. Insight is a clinical concept, which does not feature explicitly in the legal tests for DMC (although it is arguably subsumed within 'appreciation'). The relation between insight and DMC poses particular conceptual difficulties because (Owen *et al.* 2009*b*) a key component of a person's autonomy is the right to refuse treatment when one has DMC. In effect, this means that the individual, whose decision-making is unimpaired, has the right for their disagreement with their clinician concerning the nature or treatment of their illness to be respected. Yet lack of insight is a clinical phenomenon, which comprises non-acknowledgement of illness (David, 1990), due to a *specific pathological process of the illness itself*, and which often manifests itself as treatment refusal. A judgement as to whether treatment refusal stems from the values and beliefs of someone with DMC or from lack of insight depends, primarily, on the judgement of the clinician (Owen *et al.* 2009*b*). In the context of a person with a severe mental illness who is refusing treatment, there are understandable legal concerns if treatment refusal is equated with lack of DMC-T. At the same time, lack of insight is a common and core element of psychosis (David, 1990), which can, as our review demonstrates, have a substantial impact on DMC. These conceptual complexities are a natural corollary of mapping a medico-legal test onto clinical concepts.

The finding of associations between total symptoms (measured as PANSS total score or BPRS), negative symptoms and dimension scores is as we might expect, although it is curious that evidence is less convincing for DMC-T than DMC-R. The lack of association between positive symptoms and dimension scores in DMC-T and DMC-R is an interesting finding, which runs counter to anecdotal clinical experience and requires further investigation. These findings may be due to few participants with severe positive symptoms of psychosis being recruited for studies – many studies systematically excluded severely unwell people, either directly (through requiring vetting from the treating clinician), or indirectly (through recruiting in stable outpatient settings or setting a threshold of understanding or DMC for involvement in the primary study itself). Another possibility is that severe positive symptoms themselves (such as persecutory delusional beliefs) may result in participation refusal.

Given that studies investigating DMC are vulnerable to this selection bias, we consider it important that studies are designed to recruit from homogenous settings or disorders and minimise selection bias for participants with severe illness or lacking DMC-R for the study itself. A few studies have tackled this by collecting data on non-participants (Cairns *et al.* 2005; Owen *et al.* 2009*a*, 2011; Skipworth *et al.* 2013), but none have presented data on the symptom profile of non-participants in order to investigate further the lack of reported associations with DMC and positive symptoms.

There was evidence that better neurocognitive performance was positively associated with DMC-T. The evidence for this association in DMC-R was stronger, where better neurocognitive performance was highly positively associated with 'understanding' and, to a lesser extent, with 'appreciation' and 'reasoning'. This could suggest that a decision about participation in research presents a greater cognitive burden than DMC-T. If this is the case, it has implications for how information should be presented to potential participants. There is already evidence that educational (Dunn *et al.* 2002) and multimedia interventions (Jeste *et al.* 2009) can improve DMC-R in people with psychosis, mainly through enhancing 'understanding'. An alternative possibility is that, whereas a DMC-R testing paradigm is likely to present new information, within a DMC-T study, 'understanding' may already have been supported through treatment discussions in years of clinical interactions.

Methodological limitations

Sample size between studies varied considerably, with the exception of one outlier study with $n = 1447$, the range was $n = 2$–192 with a median of 37.5, interquartile range 42. The majority of studies did not provide information on sampling frames and recruitment rates. Although some provided information on non-participants (Cairns *et al.* 2005; Owen *et al.* 2009*a*, 2011; Skipworth *et al.* 2013), this was for people of all diagnoses and hence could not be used specifically to refer to people with schizophrenia.

Inappropriate statistical analyses were often employed in source publications. Within the DMC-T studies there were many studies with substantial biases or study specific features, such as the assessment of DMC-T for unrelated medical treatment or the restriction of sampling to those referred for a

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secondary opinion of DMC-T or those refusing treatment (see Table 1 and online supplemental data table).

The review was limited by significant heterogeneity between studies, with differences between the outcome tools used, the decisions in relation to which DMC was assessed and the sampled populations. For the analysis of DMC proportions, such differences were managed through stratifications using narrow inclusion criteria. For the analysis of factors associated with DMC, given the extensive differences between all studies, stratification of analysis was not possible and all studies were therefore considered. Accordingly, due to possible confounders, we would recommend that these results are interpreted with caution.

The decision-specificity of DMC is an important source of the heterogeneity within the literature. Even for clearly defined decisions around, for example, treatment for schizophrenia, the precise nature of the decision, such as Electro-Convulsive Therapy *v.* antipsychotic treatment with clozapine, may lend itself to different vulnerabilities in the different abilities that make up DMC. While cognitively demanding decisions may require better performance on 'understanding' and 'reasoning', there is limited ability to compare the dimensional measures accordingly between studies.

The nature of the decision in relation to which DMC-R was tested requires special comment. It is important to point out that many of the DMC-R studies tested decisions relating to research which could not be considered as schizophrenia-specific, but which concerned a generic treatment, aimed at a general population. Several tested DMC-R concerning a trial of an experimental drug, which may help cognitive deficits, both in schizophrenia and in normal ageing. This decision, therefore, related to non schizophrenia-specific therapeutic research, where the salience of the decision to their present symptoms would vary substantially between participants and where the role of insight and other factors was unclear and not homogenous. The contribution of these studies to understanding DMC-R in schizophrenia in relation to therapeutic research for schizophrenia is thus unclear. Decisions around research participation for therapeutic or non-therapeutic research may also pose different challenges, given the different risk/benefit profiles for the individual, and may therefore further complicate direct comparison between studies.

As a consequence there remains a need to unpick, which what abilities are global, impacting decision-making in general, and which are specific to the particular decision in hand. We hypothesise that lack of insight into one's illness would be relatively circumscribed to decisions around treatment or life consequences of the functional deficits of the illness through impact on 'appreciation', compared with symptoms such as 'thought disorder', which may affect decision making more generally through impact on 'understanding'.

The effect of publication bias on this review is unclear. Funnel plots are difficult to do with this data but as most studies report simple proportions and/or multiple association analysis there are no strong reasons to suspect publication bias.

Categorical v. *dimensional measures of DMC*

The majority of studies we found used 'dimensional scores' for their measurements of DMC. The 'judgment standard' when used, was used in isolation or guided by tools using 'dimensional scores'.

Dimensional measures of DMC take an overly siloed view of the DMC construct, and it is likely these abilities are not independent of each other. It is clear from our work that poor performance on different individual measures can impact others (if there are profound deficits on 'understanding', then there will be resultant deficits on 'appreciation' or 'use or weigh'; conversely in people with low insight this can be a total barrier to discussing the nature of their illness, even in abstract, and result in serious doubts about their resultant 'understanding'). This creates a hierarchical element to dimensional measures of DMC, in that sufficient performance on one ability is pre-requisite to performance on other abilities.

Dimensional measures can in some situations be relatively insensitive to deficits that categorical measures can detect. Some elements of psychopathology can be highly circumscribed, and have marked impact on DMC as measured by a categorical standard, but relatively less impact on dimensional measures. For example, an isolated delusional belief that participation within a research study will cure the participant of all illness may result in partially reduced scores on 'appreciation' and 'reasoning' when assessed using the framework of the MacCAT-CR, but a clear lack of DMC-R when using a 'judgement standard'. Given the limitations to using dimensional measures in isolation, we recommend that future research employ both dimensional and judgement measures of DMC.

Conclusions

We found that a significant proportion of people with schizophrenia, even on inpatient wards, have DMC, that DMC is associated with clinically relevant variables, such as insight and neurocognitive performance, and that DMC is not related to socio-demographic factors.

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There have been many studies investigating DMC in schizophrenia in the past two decades. To our knowledge, this is the most methodologically rigorous attempt to synthesise the findings from these studies, and one that was not limited to one standard of assessment of DMC or one type of decision for which DMC was assessed such as DMC-T or DMC-R. This review is the first to overview the field, and draws broad conclusions regarding the proportion and associations of DMC in schizophrenia and compare and contrast these for DMC-T and DMC-R. It is clear, however, that the complexity of the DMC construct resulting from its decision-specificity and the dimensional and categorical approaches to measuring it renders the literature diverse. Arguably it is in disarray. In order to develop our understanding of DMC in schizophrenia future quantitative research should involve comparative studies of DMC, using both dimensional and categorical measures, and provide data on non-participants and sampling-frames. Otherwise the time and decision-specific nature of DMC may lead to study-specificity, which renders systematic review impossible.

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Supplementary material

For supplementary material accompanying this paper visit https://doi.org/10.1017/S0033291717000502.

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