

# How is informed consent related to emotions and empathy? An exploratory neuroethical investigation

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## ABSTRACT

**Context** Informed consent is crucial in daily clinical practice and research in medicine and psychiatry. A recent neuroethical investigation explored the psychological factors that are crucial in determining whether or not subjects give consent. While cognitive functions have been shown to play a central role, the impact of empathy and emotions on subjects' decisions in informed consent remains unclear.

**Objective** To evaluate the impact of empathy and emotions on subjects' decision in informed consent in an exploratory study.

**Design** Decisional capacity and informed consent to a subsequent imaging study were evaluated with the MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR). Empathy and emotion recognition were measured with the Multifaceted Empathy Test (MET) and the Florida Affect Battery (FAB).

**Setting** Psychiatric subjects were recruited from a general psychiatric hospital and a forensic state hospital.

**Patients** A mixed group of 98 healthy men and forensic and non-forensic psychiatric subjects were investigated.

**Results** Both empathy (MET) and emotion recognition (FAB) correlated with MacCAT-CR scores. Higher cognitive empathy and good emotion recognition (compared with low empathy and emotion recognition) were associated with increased decisional capacity and higher rates of refusal to give informed consent.

**Conclusions** This study shows an empirical relationship between decision-making and informed consent, on the one hand, and emotions and empathy on the other. While this study is exploratory and preliminary, the findings of a relationship between informed consent, emotions and empathy raise important neuroethical questions with regard to an emotional-social concept of informed consent and potential clinical implications for testing informed consent.

## INTRODUCTION

Informed consent is crucial in everyday clinical work in all fields of medicine and also in clinical scientific studies on healthy subjects as well as on medical and psychiatric patients.<sup>1 2</sup> This has led to extensive research into the psychological functions that determine the decisions made by subjects—that is, whether they consent, refuse or remain ambivalent about participation.<sup>3–10</sup>

Decision-making is regarded as a crucial psychological process in informed consent.<sup>5 6 9 11–17</sup> It is a complex process that involves both cognitive and affective functions, as highlighted in recent neuroscientific research.<sup>3 18</sup> Cognitive functions in decision-making involved in informed consent, the

so-called 'decisional capacity', include understanding, appreciation and reasoning which may be related to attention, working memory and executive functions.<sup>5 6 9 11–17</sup> These cognitive functions and thus the decisional capacity in informed consent have recently been quantified and systematically investigated using the MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR).<sup>4 10 13 19 20</sup>

In addition to cognitive functions, decision-making also involves emotion.<sup>3 7 18 21–23</sup> The concept of emotion is a complex construct that contains both affective and cognitive components (see Panksepp 1998, 2005). Affective components concern emotional feelings and also emotional expression while cognitive functions concern the identification of emotions with their subsequent awareness and recognition as such. Cognitive functions of emotions may be crucial in regulating affective components (Ochsner *et al* 2004). Owing to the apparently complex interplay between affective and cognitive components in decision-making, one may also hypothesise a relationship between decision-making in informed consent and the affective and cognitive components of emotions. Since, however, the relationship between affective and cognitive functions of emotions has not been investigated in the specific case of decision-making in informed consent, this hypothesis is as yet only exploratory.

One peculiarity in the case of decision-making in informed consent is the encounter with the person who explains and wants to obtain the informed consent. This makes it likely that the decision by the consenting subject may also be impacted by his/her perception of the person obtaining the consent which, in turn, may be traced back to empathy. The concept of empathy describes the capability to share another person's cognitive and emotional inner life and to recognise its emotional states.<sup>3 24–26</sup> Empathic sharing and emotion recognition between the subject and the investigator may be crucial in determining decisional capacity and ultimately the decision itself—that is, whether the subject gives or refuses consent (or remains ambivalent). However, this hypothesis remains to be tested.

The general aim of our exploratory study was to investigate the impact of empathy and emotion on decisional capacity and informed consent in a mixed heterogeneous sample of healthy and psychiatric subjects. Since our study was exploratory, we selected a heterogeneous and mixed sample of healthy and psychiatric subjects and employed general tests for emotion and empathy. We first aimed to investigate whether empathy and

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emotions are related to the decisional capacity as measured with the MacCAT-CR. We then investigated whether empathy and emotions are related to the subjects' decision—that is, whether they approve, refuse or remain ambivalent concerning study participation. We hypothesised that empathy and emotions are related to the subjects' decisional capacity and their decision on informed consent (approval, refusal or ambivalence). Decisional capacity was tested with the MacCAT-CR while empathy and emotions were measured using standardised and well-established tests—the Multifaceted Empathy Test (MET)<sup>24</sup> and the Florida Affect Battery (FAB).<sup>26</sup>

## METHODS

### Subjects

We investigated 98 men of mean±SD age 34.2±10.6 years (range 19–66). In order to account for a heterogeneous distribution in our study group mirroring the exploratory nature of our study, we included both healthy subjects and different psychiatric groups of patients. We included 16 healthy subjects, 16 non-forensic schizophrenic patients, 35 forensic schizophrenic patients and 31 forensic patients with personality disorder. One participant out of the forensic schizophrenic patients refused to continue the testing after finishing the MacCAT-CR interview. Forensic patients were recruited from inpatients at the Forensic Psychiatric Hospital Uchtspringe, Germany while non-forensic patients were recruited from the Department of Psychiatry at the University of Magdeburg, Germany. Inclusion criteria for psychiatric subjects were a psychiatric diagnosis of schizophrenia or personality disorder according to DSM IV-R as established by independent clinicians (JW and UG) on the basis of a clinical interview and the willingness to be asked for possible consent into a subsequent real imaging study. The patients were approached by JW and UG and asked whether they would be willing to be considered for an interview and testing about possible participation in a subsequent real imaging study. If the patients approved, they were interviewed by AV. The subsequent imaging study was an fMRI study on the neural correlates of aggressive impulses and memory retrieval in forensic and non-forensic psychiatric patients; the imaging study team remained completely independent of the team for the present investigation. Exclusion criteria for the psychiatric sample was the refusal to take part in the interview and testing, mental retardation and patients with affective disorders (eg, major depressive disorder) and cognitive disorders (eg, dementia). Inclusion criteria for the healthy subjects included the absence of any psychiatric, neurological and medical conditions (as checked for by routine psychiatric (following DSM IV-R) and medical examination performed by AV). Exclusion criteria for the healthy subjects included unwillingness to take part in the interview and mental retardation. In order to exclude mental retardation, all subjects (both healthy and psychiatric) were tested with the German Wortschatztest (WST)<sup>27</sup> a well-standardised measure of general intelligence. Only men were included in the study to avoid any possible gender effects.

After feedback from the local Institutional Review Board (IRB), no separate consent was required for the present study which was approved by the local IRB as part of the subsequent imaging study.

### Measurement of decisional capacity, empathy and emotion recognition

Decisional capacity was measured using the MacCAT-CR<sup>10</sup> in a German version.<sup>28</sup> The MacCAT-CR is a standardised

instrument for evaluating decisional capacity in informed consent for clinical research. The test uses a semi-structured interview format with questions tailored specifically for the research project in question which, in our study, concerned a combined EEG/fMRI investigation. The investigator of the MacCAT-CR (AV) was trained and supervised and independent of both the clinicians (JW, UG) recruiting the sample and the investigators of the subsequent imaging study. Since our focus was on cognitive and emotional functions, we used only the subscores of understanding and reasoning of the MacCAT-CR while neglecting its third subscore, appreciation. Moreover, to avoid confounding by bias, data analysis in the present study was done by an investigator (AS) who was independent of both the investigator of the informed consent study (AV) and the clinicians (JW, UG).

The MET was used to examine different aspects of empathy. It is a well-established tool for the multidimensional measurement of empathy with separate assessment of emotional and cognitive aspects of empathic functioning.<sup>24</sup> The version used in this study consisted of a set of 23 different photographs depicting persons expressing a certain emotion. While looking at the pictures, subjects were asked to answer a series of questions concerning their perception of the emotional states depicted as well as their emotional and empathic reaction. The MET contains several subtests that concern either more affective (ie, implicit and explicit emotion expression) or more cognitive (cognitive empathy) subscores (table 1).

To test for emotion recognition and identification, we applied parts of the German version of the FAB.<sup>26</sup> The FAB is sensitive for the acquisition of deficits in affective processing and tests for identification and recognition of emotion in either visual (FAB 2, 3, 5) or auditory (FAB 6, 7, 8a, 8b) mode. The emotions of interest are divided into five categories: joy, sadness, anger, fear, neutral. The test scores for each subtest were estimated as correct answers as percentages. For further evaluation we created two groups by pooling the results of FAB 2, 3 and 5 (FAB visual) and the results of FAB 6, 7, 8a and 8b (FAB auditory), respectively.

### Data analysis

For data analysis we divided the whole sample, independent of the clinical diagnosis, according to the subjects' decision about participation in the clinical trial described during the interview. Three groups were created: 44 subjects gave consent to participation (33.7±11.4 years; range 20–66), 33 refused participation (34.1±9.9 years; range 19–59) and 21 were ambivalent (35.4±10.4 years; range 22–59). No significant difference was seen in the age of the patients in the three groups. To test for possible differences in general intelligence between the participants, subtest 13 of the WST test was applied<sup>27</sup>; no significant differences were found in cognitive function between the three groups.

Statistical analyses were performed using SPSS Version 15. For correlation analyses we calculated the Pearson correlation coefficient for normally distributed data and the Spearman correlation coefficient for data not distributed normally (as shown by the Kolmogorov–Smirnov test). To compare the distribution of the decisional categories (approval, ambivalence, refusal), we divided the whole sample into two groups (high vs low). We first calculated the mean value for the respective variable and used this score as a cut-off value to divide the group into two subgroups (high and low).

To compare high versus low understanding we calculated the mean MacCAT-CR understanding scores of the whole group (MacCAT-CR understanding<sub>mean</sub>=6.9). This score served as a cut-off to divide the group into 'high understanding' and 'low

**Table 1** Statistical analysis of the correlation of emotion and empathy measures with decisional capacity and with each other

<b>A: Statistical analysis of the correlation of emotion recognition with decisional capacity</b>		
Spearman correlation	Result	Significance
FAB × MacCAT_CR:		
FAB visual × MacCAT_CR understanding	$R_s(97)=0.348; p<0.001$	**
FAB auditory × MacCAT_CR understanding	$R_s(97)=0.328; p=0.001$	**
FAB visual × MacCAT_CR reasoning	$R_s(97)=0.273; p=0.007$	*
FAB auditory × MacCAT_CR reasoning	$R_s(97)=0.431; p<0.001$	**
<b>B: Statistical analysis of the correlation of empathy measures with decisional capacity</b>		
Spearman correlation	Result	Significance
MET × MacCAT_CR:		
MET EEI × MacCAT_CR understanding	$R_s(97)=-0.091; p=0.374$	NS
MET EEE × MacCAT_CR understanding	$R_s(97)=-0.132; p=0.196$	NS
MET CE × MacCAT_CR understanding	$R_s(97)=0.320; p=0.001$	**
MET mirroring × MacCAT_CR understanding	$R_s(97)=-0.113; p=0.270$	NS
MET intensity × MacCAT_CR understanding	$R_s(97)=-0.209; p=0.040$	*
MET valence × MacCAT_CR understanding	$R_s(97)=0.105; p=0.304$	NS
MET EEI × MacCAT_CR reasoning	$R_s(97)=-0.129; p=0.207$	NS
MET EEE × MacCAT_CR reasoning	$R_s(97)=-0.176; p=0.086$	(*)
MET CE × MacCAT_CR reasoning	$R_s(97)=0.150; p=0.142$	NS
MET mirroring × MacCAT_CR reasoning	$R_s(97)=-0.177; p=0.084$	(*)
MET intensity × MacCAT_CR reasoning	$R_s(97)=-0.170; p=0.096$	(*)
MET valence × MacCAT_CR reasoning	$R_s(97)=-0.039; p=0.704$	NS
<b>C: Statistical analysis of the correlation of cognitive and affective empathy measures with emotion recognition measures</b>		
Pearson correlation	Result	Significance
MET × FAB:		
MET EEI × FAB visual	$R(97)=-0.301; p=0.003$	*
MET EEE × FAB visual	$R(97)=-0.384; p<0.001$	**
MET CE × FAB visual	$R(97)=0.502; p<0.001$	**
MET mirroring × FAB visual	$R(97)=-0.337; p=0.001$	**
MET intensity × FAB visual	$R(97)=-0.295; p=0.003$	*
MET valence × FAB visual	$R(97)=0.022; p=0.830$	NS
MET EEI × FAB auditory	$R(97)=-0.280; p=0.005$	*
MET EEE × FAB auditory	$R(97)=-0.408; p<0.001$	**
MET CE × FAB auditory	$R(97)=0.533; p<0.001$	**
MET mirroring × FAB auditory	$R(97)=-0.365; p<0.001$	**
MET intensity × FAB auditory	$R(97)=-0.392; p<0.001$	**
MET valence × FAB auditory	$R(97)=0.067; p=0.513$	NS

\*\* $p\leq 0.001$ ; \* $p\leq 0.05$ ; (\*) $p\leq 0.1$ .

CE, cognitive empathy; EEE, emotion empathy explicit; EEI, emotion empathy implicit; FAB, Florida Affect Battery; MacCAT\_CR, MacArthur Competence Assessment Tool for Clinical Research; MET, Multifaceted Empathy Test; NS, not significant.

understanding' subgroups. We used the same procedure for high versus low empathy and emotion comparisons. Subsequent statistical comparison of the distribution of the decisional categories in these two subgroups was performed using  $\chi^2$  tests.

## RESULTS

### Relationship of decisional capacity to empathy and emotion recognition

We observed a positive correlation of both FAB visual and FAB auditory scores with the MacCAT-CT understanding and

reasoning results (figure 1A and table 1A). Hence, emotion recognition seems to be related to the capacity to understand and reason in informed consent.

The cognitive empathy score (MET CE) showed a significantly positive correlation with MacCAT-CT understanding. In contrast to cognitive empathy, a subscore of affective empathy (MET intensity) correlated negatively with MacCAT-CT understanding (figure 1B and table 1B). The relevance of MET intensity was further underlined by its marginally significant negative correlation with MacCAT-CT reasoning. Two other markers of affective empathy (MET mirroring and MET EEE) also showed a marginally significant negative correlation with MacCAT-CT reasoning.

However, these relationships concerned only selective subscales of the MET (ie, cognitive empathy, intensity mirroring and EEE) and predominantly the subscore of understanding from the MacCAT-CR, while others (on both sides, MET and MacCAT-CR) did not show a significant relationship.

Finally, we correlated measures of empathy and of emotion recognition with each other. Here, the cognitive measure of empathy (MET CE) showed a significantly positive correlation with both measures of emotion recognition (FAB auditory and visual)—the better the cognitive component of empathy, the better the emotion recognition. However, the affective measures of empathy (MET mirroring and others) showed a significantly negative correlation with emotion recognition (figure 1C, D and table 1C)—the stronger the affective component of empathy, the worse the emotion recognition. Generally, almost all subscales of the MET correlated with the FAB, which contrasts with the correlation between MET and MacCAT-CR where only some MET subscales showed a correlation (table 1).

Taken together, these findings indicate that empathy—especially its cognitive component—and emotion recognition relate to decisional capacity in informed consent in a positive way while affective components of empathy such as mirroring and intensity, mirroring and EEE are related to the decisional capacity (and emotion recognition) in a negative way.

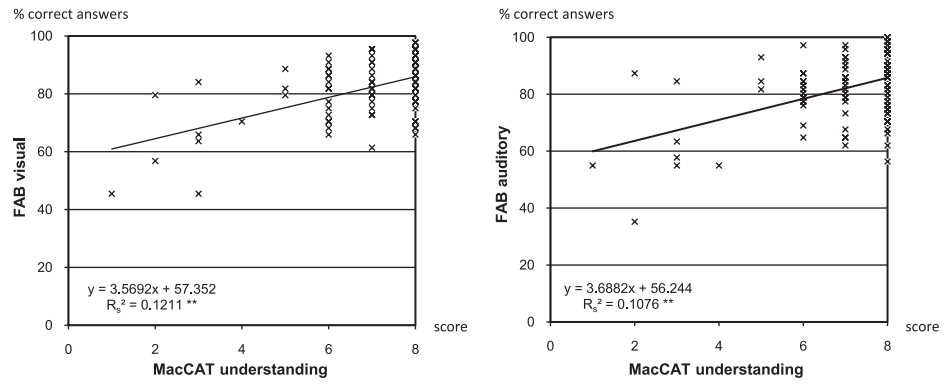
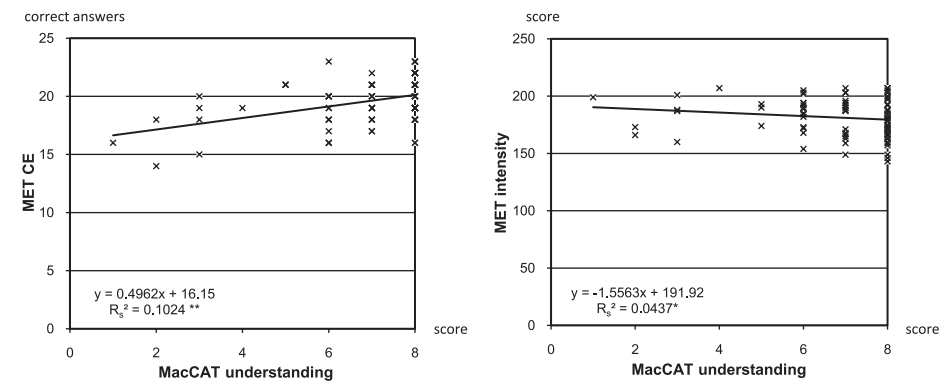
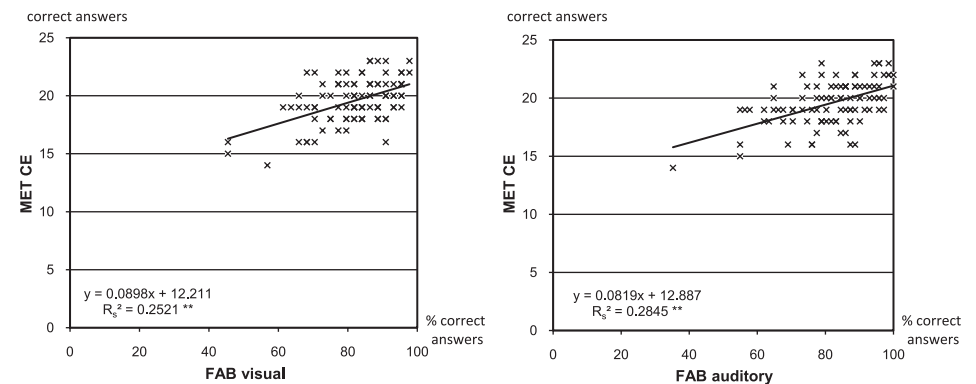
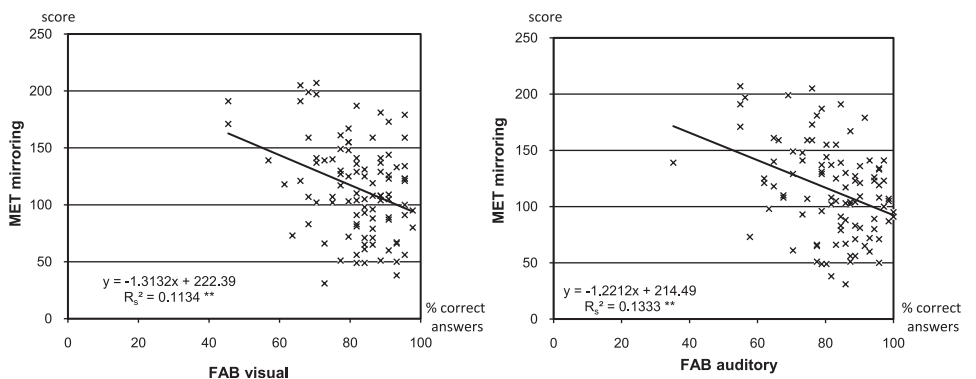
### Relationship of informed consent to decisional capacity, empathy and emotion recognition

We then investigated the impact of decisional capacity, empathy and emotion recognition on the decision of informed consent (approval, refusal, ambivalence). For that we compared the distribution of the three consent groups within groups of high and low scoring subjects (high and low MET, FAB and MAC-CAT). We first calculated the mean MacCAT-CR understanding scores of the whole group (MacCAT-CR understanding  $_{\text{mean}}=6.9$ ). This score served as a cut-off to divide the group into a high understanding subgroup (MacCAT-CR understanding high:  $n_{\text{MacCAT-CR understanding} \geq 6.9}=70$ ) and a low understanding subgroup (MacCAT-CR understanding low:  $n_{\text{MacCAT-CR understanding} < 6.9}=28$ ). The same procedure was applied for high versus low empathy and emotion comparisons.

Comparison of the high versus low MacCAT understanding groups revealed a higher approval rate among high scoring subjects (figure 2A and table 2 in online supplement). A comparison of high and low MET CE groups showed that high CE scoring subjects had a higher refusal rate and low scoring subjects had a higher ambivalence rate, with very little difference in the rate of approval (see figure 2B and table 2B in online supplement). A comparison of high and low MET emotion empathy implicit (EEI) groups showed conflicting results with high scoring subjects having a higher ambivalence rate than low scoring subjects (see figure 2B and table 2B in online supplement).

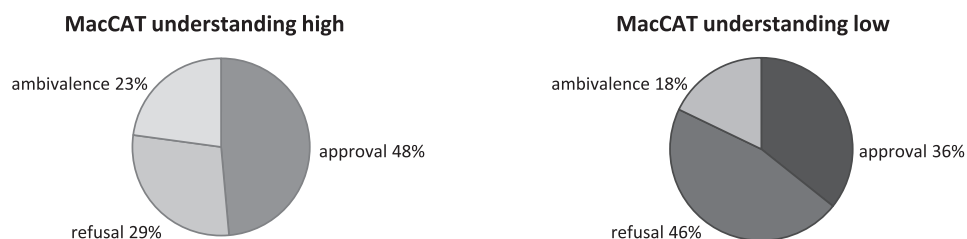
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**Figure 1** Graphic representation of the correlation of (A) emotion and (B) empathy measures with decisional capacity as measured by the MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR) and (C, D) between each other. A positive correlation was found between Florida Affect Battery (FAB) visual and auditory scores and the MacCAT-CR understanding scores (A). Investigating of the correlation between empathy and decisional capacity, a positive correlation was found between the Multifaceted Empathy Test cognitive empathy (MET CE) subscore and MacCAT-CR understanding scores and a negative correlation was found between the MET intensity subscore and MacCAT-CR understanding scores (B). Both affective and cognitive empathy measures were correlated with emotion recognition, albeit in opposite directions (C,D). \*\* $p \leq 0.001$ ; \* $p \leq 0.05$ .

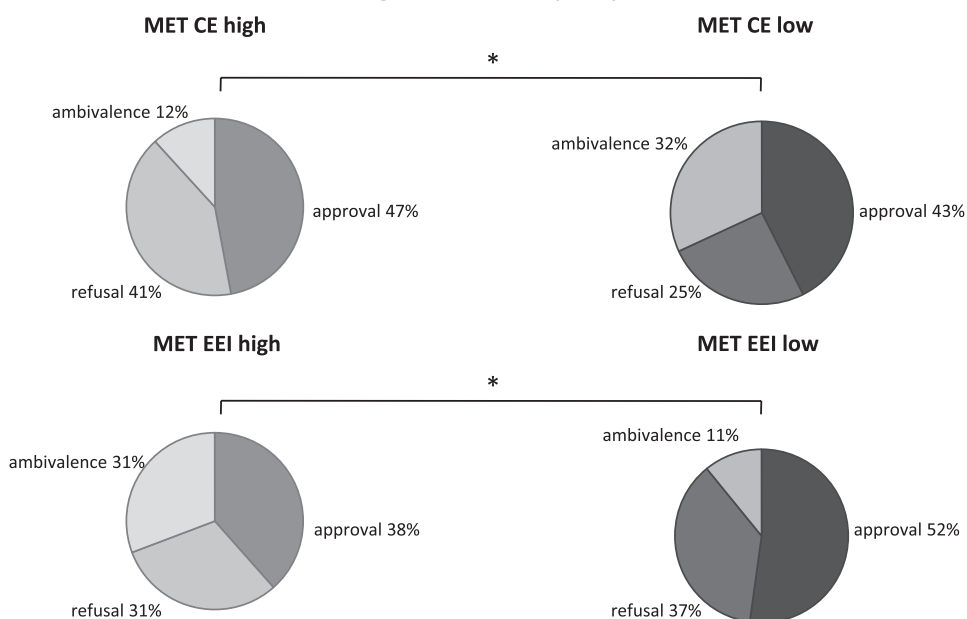
**A: Correlation of emotion recognition with decisional capacity****B: Correlation of empathy measures with decisional capacity****C: Correlation of cognitive empathy measures with emotion recognition****D: Correlation of affective empathy measures with emotion recognition**

**Figure 2** Distribution of the three consent categories (approval, refusal, ambivalence) in (A) high and low understanding, (B) empathy and (C) emotion groups. A significant difference was seen between the group with a high MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR) understanding score (nMacCAT understanding  $\geq 6.9=70$ ) and those with a low MacCAT understanding score (nMacCAT understanding  $< 6.9=28$ ) ( $\chi^2(2)=11.671$ ;  $p=0.003$ ) with a higher approval rate among the high MacCAT-CR understanding subjects and a higher refusal rate among the low MacCAT-CR understanding subjects, respectively. A significant difference was also seen between the group of subjects with a high Multifaceted Empathy Test cognitive empathy (MET CE) score (nMET-CE  $\geq 20=51$ ) and the group with a low MET CE score (nMET CE  $< 20=47$ ) ( $\chi^2(2)=23.112$ ;  $p<0.001$ ) with a higher refusal rate among those with a high MET CE score than in those with a low MET CE score.

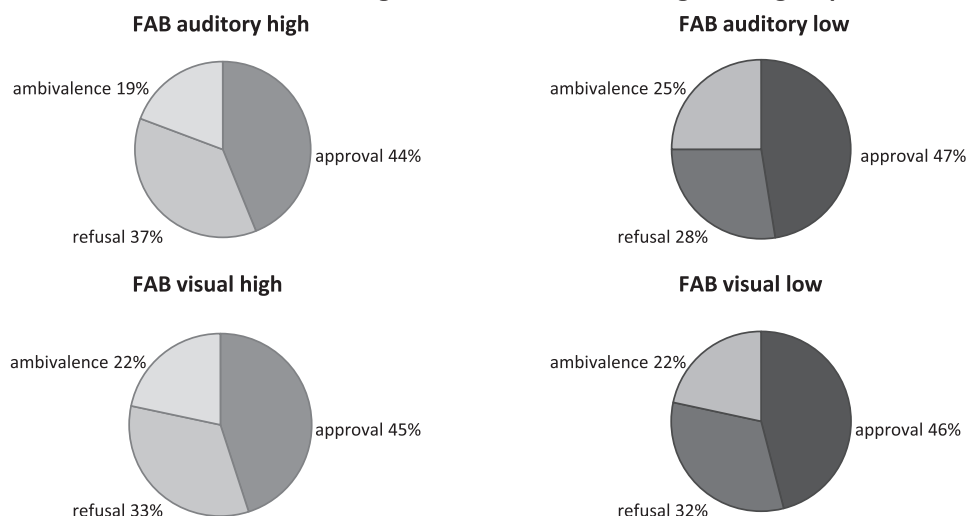
### A: Distribution of consent in high and low understanding groups



### B: Distribution of consent in high and low empathy groups



### C: Distribution of consent in high and low emotion recognition groups



Although high scoring subjects in the auditory emotion recognition task (FAB auditory) had higher refusal rates than low scoring FAB subjects, this effect was not statistically significant (see figure 2C and table 2C in online supplement).

Taken together, these findings indicate that decisional capacity and empathy seem to have an impact on the decision of subjects in informed consent—that is, whether they approve, refuse or remain ambivalent concerning their willingness to participate in a subsequent imaging study.

## DISCUSSION

This exploratory study shows that empathy and emotion are related to subjects' decisional capacity and informed consent. Higher cognitive empathic abilities and good emotion recognition were related to increased decisional capacity and higher refusal rates. Although preliminary and exploratory, our results suggest that subjects' ability to empathise with and recognise others' emotions impacts on their decision-making in informed consent. If confirmed and further specified in future studies, this

yields neuroethical questions concerning the daily medical practice of obtaining informed consent, the criteria employed by the IRBs and the concept of informed consent itself.

### Empirical results

Our first main finding is that the decisional capacity in informed consent is associated with emotion and empathy. More specifically, a better ability to identify and recognise emotions in others was related to higher scores of understanding and reasoning in decision-making of informed consent. This is in accordance with the postulated relevance of emotions in decision-making, thus confirming these theoretical conceptual assumptions on an empirical basis.<sup>3 7 22 23</sup> Since our study is exploratory, our results can only be considered as preliminary and further specification is needed in a more homogeneous sample with more detailed and specific tests of emotional function that may then also distinguish between affective and cognitive components (Panksepp 1998).

In addition to emotions, we also observed a relationship between decisional capacity and empathy. The better the consenting subjects were able to empathise with other people (as tested by MET), the higher their scores in the MacCAT-CR. Interestingly, this applied only to the cognitively-oriented subscore of the MET (ie, cognitive empathy) while other more affective components (ie, intensity, mirroring and EEE correlated negatively). The selective nature of the relationship between empathy and decisional capacity is even more remarkable given the fact that almost all subscales of the MET correlated with our emotion measure (FAB). Furthermore, the correlation with empathy concerned mainly one subscore of the MacCAT-CR (understanding) and showed no relation with others. Taken together, this suggests that empathy may be related to the decisional capacity involved in informed consent in a very special way. Our finding must be considered preliminary and exploratory and requires confirmation and specification in future studies.

Further differentiation into cognitive and affective components of empathy may also be necessary. High cognitive empathic abilities (as measured by the MET CE score) have a positive impact on decisional capacity by enhancing it, while high affective empathic abilities (as measured by MET mirroring, explicit emotion and intensity scores) are negatively related to decisional capacity, showing inhibitory rather than enhancing effects. This is compatible with Charland's theoretical assumptions that postulate both positive and negative roles of emotions and empathy in informed consent.<sup>7</sup> The differential role of affective and cognitive components of empathy is further supported by our findings of their opposite correlation with emotion recognition.

Replicating previous results, higher values in the MacCAT-CR understanding section were seen in subjects with a higher approval rate compared with lower MacCAT-CR values.<sup>5 6 9 11-13 15-17</sup> Extending these results, our findings indicate that empathy seems to affect decision-making in informed consent (ie, whether a subject approved, refused or remained ambivalent concerning study participation). Subjects showing high cognitive empathy refused study participation to a significantly greater extent than those with low cognitive empathy. The impact of cognitive empathy contrasted with that of affective empathy on decisional capacity. High affective empathy led to significantly higher ambivalence in informed consent. The differential effects of cognitive and affective empathy and decisional capacity leads one to speculate that the three groups of informed consent (approval, refusal, ambivalence) may be characterised by different relationships between empathy/

emotion and decisional capacity. However, this remains rather speculative at this point and needs to be investigated in more detail. While adequate for the exploratory and preliminary nature of our study, future studies need to investigate more homogeneous samples and employ more specific and detailed measures of emotions and empathy. Hence, our results need to be considered preliminary, awaiting future confirmation and specification.

### Neuroethical questions

If confirmed in future studies, these results raise several neuroethical issues including the selection of subjects to be examined in clinical trials and the validity of informed consent in general. Especially subjects with high cognitive and low affective empathic abilities could be selected for study participation in order to gain a higher approval rate in informed consent. This bias in selecting subjects for study participation may be ethically problematic, however, because it artificially minimises the risk of refusal (or ambivalence). Hence, IRBs may want to develop and employ criteria for the selection of subjects with regard to empathy and emotion.

Another ethical problem concerns the impact of the investigator. The outcome of informed consent is usually considered to be solely dependent upon the subject while the emotions and empathic abilities of the investigator have no effect. If, however, empathy and emotion play a major role in determining the outcome of informed consent, the lack of effect of the emotional and empathic characteristics of the investigator becomes questionable. Analogous to the subjects, the empathic and emotional abilities of the investigator and probably his/her sympathy may determine the outcome of the informed consent; this needs to be investigated in future studies.

If the investigator's emotion, empathy and sympathy do indeed have an impact, one may bias the outcome of the informed consent by selecting those with high empathic skills and sympathy in order to artificially increase subjects' approval rate. This may be ethically problematic, so IRBs may want to develop and employ criteria for selection of the investigator with regard to empathy and emotion. This means that we may need to develop an emotional-social investigator-dependent concept of informed consent, as distinguished from the current consent that is rather cognitive and remain investigator-independent.

Our results are also of particular relevance for the validity of informed consent in psychiatric patients. Patients with psychiatric disorders such as schizophrenia, depression and personality disorders are well known to show dysfunction in both cognitive and affective components of empathy. This in turn may strongly impact their ability to give valid informed consent. From an ethical point of view, our results therefore question the hitherto predominance of cognitive functions in judging the validity of subjects' informed consent. Severe empathic and emotional deficits may confound the subjects' informed consent to a great extent, even if their cognitive skills are preserved as, for instance, in personality disorders and neurosis. Future investigation may therefore focus also on patients with such disorders and show the interaction between affective and cognitive functions in informed consent as well as with their specific psychopathological symptoms.

### CONCLUSION

These preliminary exploratory findings indicate a relationship between the decisional capacity in informed consent and empathy and emotions in the consenting subjects. This suggests

that empathy and emotion may be crucially involved in decisional capacities in informed consent. If confirmed and specified, these findings raise several neuroethical questions that concern the procedure by which informed consent is obtained in daily medical practice and research, the concept of informed consent, and the criteria employed by IRBs in evaluating study proposals.

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**Competing interests** None.

**Patient consent** Obtained.

**Ethics approval** This study was conducted with the approval of the local Institutional Review Board (IRB).

**Contributors** GN devised and designed the study and supervised the whole project. AS and GN collaborated on the writing of the manuscript. Data acquisition was done by AV. AS and AV collaborated on adaptation of all tests being used in this study. Data analysis was performed by AS. Recruitment of psychiatric subjects was by JW and UG under the supervision of JW.

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## REFERENCES

1. **Appelbaum PS.** Clinical practice. Assessment of patients' competence to consent to treatment. *N Engl J Med* 2007;**357**:1834–40.
2. **Annas GJ.** Globalized clinical trials and informed consent. *N Engl J Med* 2009;**360**:2050–3.
3. **Northoff G.** Neuroscience of decision making and informed consent: an investigation in neuroethics. *J Med Ethics* 2006;**32**:70–3.
4. **Candilis PJ,** Geppert CM, Fletcher KE, *et al.* Willingness of subjects with thought disorder to participate in research. *Schizophr Bull* 2006;**32**:159–65.
5. **Carpenter WT Jr,** Gold JM, Lahti AC, *et al.* Decisional capacity for informed consent in schizophrenia research. *Arch Gen Psychiatry* 2000;**57**:533–8.
6. **Koren D,** Poyurovsky M, Seidman LJ, *et al.* The neuropsychological basis of competence to consent in first-episode schizophrenia: a pilot metacognitive study. *Biol Psychiatry* 2005;**57**:609–16.
7. **Charland LC.** Affective neuroscience and addiction. *Am J Bioeth* 2007;**7**:20–1.
8. **Grisso T,** Appelbaum PS, Hill-Fotouhi C. The MacCAT-T: a clinical tool to assess patients' capacities to make treatment decisions. *Psychiatr Serv* 1997;**48**:1415–19.
9. **Jeste DV,** Depp CA, Palmer BW. Magnitude of impairment in decisional capacity in people with schizophrenia compared to normal subjects: an overview. *Schizophr Bull* 2006;**32**:121–8.
10. **Appelbaum PS,** Grisso T, Frank E, *et al.* Competence of depressed patients for consent to research. *Am J Psychiatry* 1999;**156**:1380–4.
11. **Candilis PJ,** Fletcher KE, Geppert CM, *et al.* A direct comparison of research decision-making capacity: schizophrenia/schizoaffective, medically ill, and non-ill subjects. *Schizophr Res* 2008;**99**:350–8.
12. **Palmer BW,** Jeste DV. Relationship of individual cognitive abilities to specific components of decisional capacity among middle-aged and older patients with schizophrenia. *Schizophr Bull* 2006;**32**:98–106.
13. **Stroup S,** Appelbaum P, Swartz M, *et al.* Decision-making capacity for research participation among individuals in the CATIE schizophrenia trial. *Schizophr Res* 2005;**80**:1–8.
14. **Palmer BW,** Dunn LB, Appelbaum PS, *et al.* Correlates of treatment-related decision-making capacity among middle-aged and older patients with schizophrenia. *Arch Gen Psychiatry* 2004;**61**:230–6.
15. **Howe V,** Foister K, Jenkins K, *et al.* Competence to give informed consent in acute psychosis is associated with symptoms rather than diagnosis. *Schizophr Res* 2005;**77**:211–14.
16. **Roberts LW,** Warner TD, Brody JL, *et al.* Patient and psychiatrist ratings of hypothetical schizophrenia research protocols: assessment of harm potential and factors influencing participation decisions. *Am J Psychiatry* 2002;**159**:573–84.
17. **Moser DJ,** Schultz SK, Arndt S, *et al.* Capacity to provide informed consent for participation in schizophrenia and HIV research. *Am J Psychiatry* 2002;**159**:1201–7.
18. **Damasio AR.** *The Feeling of What Happens: Body and Emotion in the Making of Consciousness.* New York: Harcourt Brace, 1999.
19. **Kovnick JA,** Appelbaum PS, Hoge SK, *et al.* Competence to consent to research among long-stay inpatients with chronic schizophrenia. *Psychiatr Serv* 2003;**54**:1247–52.
20. **Jeste DV,** Palmer BW, Golshan S, *et al.* Multimedia consent for research in people with schizophrenia and normal subjects: a randomized controlled trial. *Schizophr Bull* 2009;**35**:719–29.
21. **Northoff G,** Grimm S, Boeker H, *et al.* Affective judgment and beneficial decision making: ventromedial prefrontal activity correlates with performance in the Iowa gambling task. *Hum Brain Mapp* 2006;**27**:572–87.
22. **Breden TM,** Vollmann J. The cognitive based approach of capacity assessment in psychiatry: a philosophical critique of the MacCAT-T. *Health Care Anal* 2004;**12**:273–83; discussion 265–72.
23. **Kluge EH.** Competence, capacity, and informed consent: beyond the cognitive-competence model. *Can J Aging Fall* 2005;**24**:295–304.
24. **Dziobek I,** Rogers K, Fleck S, *et al.* Dissociation of cognitive and emotional empathy in adults with asperger syndrome using the Multifaceted Empathy Test (MET). *J Autism Dev Disord* 2008;**38**:464–73.
25. **Decety J,** Batson CD. Social neuroscience approaches to interpersonal sensitivity. *Soc Neurosci* 2007;**2**:151–7.
26. **Bowers D,** Blonder L, Heilman KM. *The Florida Affect Battery.* Gainesville, FL: Center Neuropsychological Studies, 1992.
27. **Horn W.** *L-P-S Leistungsprüfsystem.* Vol 2. Göttingen: Hogrefe, 1983.
28. **Vollmann J,** Bauer A, Danker-Hopfe H, *et al.* Competence of mentally ill patients: a comparative empirical study. *Psychol Med* 2003;**33**:1463–71.



## How is informed consent related to emotions and empathy? An exploratory neuroethical investigation

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