"ASSESSMENT OF CAPACITY TO CONSENT FOR TREATMENT IN PATIENTS SUFFERING FROM FUNCTIONAL PSYCHOSIS REQUIRING HOSPITALIZATION IN A TERTIARY CARE PSYCHIATRIC UNIT-A CROSS SECTIONAL DESCRIPTIVE STUDY"

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ACRONYMS

ACT	Assessment of Consent capacity for Treatment
AD	Advance Directive
BCIS	Beck's Cognitive Insight Scale
BPRS	Brief Psychiatric Rating Scale
CAI	Competency Assessment Interview
CATIE	National Institute of Mental Health Clinical Antipsychotic Trials of Intervention Effectiveness
CCTI	Competency to Consent to Treatment Instrument
CGI	Clinical Global Impression
CIS	Competency Interview Schedule
DADMC	Direct Assessment of Decision-Making Capacity
HCAI	Hopemont Capacity Assessment Interview
ILA	Indian Lunacy Act
MacCAT-T	First Generation Antipsychotics
MHA	Mental Health Act
MHCA	Mental Health Care Act
MHRB	Mental Health Review Board
MMSE	Mini Mental Status Examination
NMHS	National Mental Health Survey
NR	Nominated Representative
OCQ	Ontario Competency Questionnaire
PANSS	Positive and Negative Syndrome Scale

PMI	Persons with Mental Illness
PWD	Persons With Disabilities
SANS	Scale for the Assessment of Negative Symptoms
SAPS	Scale for the Assessment of Positive Symptoms
UNCRPD	United Nations Conventions on the Rights of Persons with Disabilities
UNESCO	United Nations Educational, Scientific and Cultural Organisation

ABSTRACT

Introduction: The recent introduction of the Mental Healthcare Act 2017 in India has made assessment of capacity to consent as integral part of the clinical work. However, there are no proper guidelines regarding the assessment of capacity and to the best of our knowledge, there are no studies done on this topic in India.

Objective: To assess capacity to consent to treatment in patients with functional psychosis and to also identify the factors affecting the capacity to consent to treatment.

Methods: A cross-sectional study to assess capacity to consent to treatment in 100 inpatients, with ICD-10 DCR diagnosis of psychosis admitted in psychiatry ward. MacArthur Competence Assessment Tool- Treatment (MacCAT-T) was used to assess capacity to consent to treatment. Brief Psychiatric Rating Scale (BPRS) and Beck's insight scale (BCIS) was applied for assessment of severity of psychosis and level of insight. The probable factors affecting capacity were also assessed.

Results: Twenty-three patients were found to have intact capacity to consent. Patients with impaired capacity to consent had higher BPRS scores and low Beck's insight scores. High BPRS scores were related with poor appreciation and poor expression of choice (p values <0.0001).

Conclusion: One-fourth of the patients admitted with psychosis had intact capacity to consent to treatment. Among patients with impaired capacity to consent, they had a greater severity of psychosis and poorer insight into the illness. The patients with greater severity of psychosis had poor appreciation of the illness and deficits in expression of a clear-cut choice

Keywords: Capacity to consent, MacCAT-T, Psychosis, MHCA-2017, India.

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The Laws Regarding Care And Treatment Of Persons With Mental Illness Has Seen A Lot Of Changes And Development Over The Last Few Decades. The Focus Has Gradually Shifted From Keeping Them Under Asylum Care To Safeguard The Community To Bringing Them Back To Mainstream Of Society And Protecting Their Rights And Autonomy. The Regulations Started With The Indian Lunacy Act (ILA)(1912) Which Regulated The Functioning of The Asylums. It Did Not Take Into Consideration The Rights Of Patients Admitted, Due To Which Around The Mid 1980's Developments Took Place To Include The Same. In 1987, The Mental Health Act Was Passed; It Included A Clause To Safeguard The Rights of Persons With Mental Illness And To Make It Congruent To The Constitution of The Country (Article 21- Right To Life And Liberty). However, It Gave More Powers To The Next Of Kin To Decide Regarding The Fate Of The Patient, And They Could Be Kept In The Institution For Long Without Their Due Consent. This Led To Violation Of The Rights Of The Patient And The Act Was Not In Keeping With Its Agenda Of Protecting The Rights Of The Patients With Mental Illness.

In 2015, The Mental Health Care Bill Was Proposed, Which Later Was Enacted As The Mental Healthcare Act 2017 (MHCA). MHCA 2017 Intends To Provide Mental Healthcare, Promote And Protect The Rights For Persons With Mental Illness.[1]The MHCA Dealt With The Issues Of Violation Of Rights Of The Psychiatric Patients And Was In Concordance With The United Nations Convention On The Rights Of Persons With Disabilities (UNCRPD). Thus, The Concept Of Assessment Of Capacity To Consent For Treatment, Hospitalisation, And Assistance Amongst Patients With Psychiatric Disorders Gained Importance.

Capacity To Consent Is Defined As The Ability Of An Individual To Take Decisions After Due Understanding And Weighing Of The Pros And Cons Of The Information Provided. MHCA 2017 Defines A Person To Have Intact Capacity If, The Patient Is Able To Understand The Information Provided, Appreciate The Consequences Related To The Decision And Express A Clear Choice Either Verbally Or Non-Verbally.[2]According To GrissoAnd Appelbaum(1988), There Are Four Legal Standards To For Capacity To Consent. They Are Understanding, Appreciation, Reasoning, And Communication Of Choice. Each Standard Represents A Set Of Abilities Needed To Make Decisions.[3]Capacity And Competence Are Different Terms. Capacity Is Assessed By A Clinician While, Competence Is Determined Legally By A Court Or Mental Health Review Board.

In Clinical Practice And According To Recent Laws, The Legal And Ethical Standards Must Be Kept In Mind. It Requires That A Person Should Have An Intact Capacity To Consent To Treatment.

Most Of The Times, It Is Assumed That A Person Suffering From A Psychiatric Illness, Especially Schizophrenia Or Other Psychotic Disorders Will Have Impaired Capacity To Consent. This Increases The Stigma And Violates The Rights Of The Individuals.[4]According To Studies, Only 50 % Patients Admitted With Acute Exacerbation Of Schizophrenia Have Impaired Decision Making Ability.[5]Cairns Et Al (2005), 42.8 % Psychiatric Patients Lack Treatment Related Decision Making Capacity.[6]

Since There Is Are No Studies Done In The Indian Context Regarding Capacity To Consent And Its Assessment And Given The Recent Change In Regulations Regarding Psychiatric Patients And Their Treatment, This Study Was

Taken Up. The Aim Of The Study Was To Assess The Capacity To Consent To Treatment, In Patients Suffering From Functional Psychosis And To Assess The Factors Affecting The Capacity To Consent To Treatment.

OBJECTIVES

PRIMARY OBJECTIVE-

To assess the capacity to consent for treatment, in patients suffering from functional psychosis.

SECONDARY OBJECTIVES:

To assess the factors affecting the capacity to consent to treatment.

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REVIEW OF LITERATURE

INTRODUCTION

In the National Mental Health survey (NMHS) (2015-2016), it came to light that, of psychiatric disorders in India, there is a lifetime prevalence of 13.7 % and current prevalence of 10.56%.[7] People suffering from psychiatric disorders are more at risk of harm and are exposed to manipulation and infringement of their rights .[8] To protect them from such risks and manipulations, protective mechanisms such as various laws and legislations exist.[9]

CAPACITY AND COMPETENCY

Capacity to consent, also known as mental capacity, is defined as the ability of a patient to make a legal decision. It forms an integral part of the informed consent.[10] It refers to the individuals' prowess to understand and grasp the implications of choosing the different options provided.[11]

As defined by Grisso and Appelbaum, capacity is a person's ability to, adequately perceive the intended meaning of the provided information and retention of the same (understanding); relate the information (related to the condition and treatment) to their own situation (appreciation); weigh risks, benefits, be aware of consequences of the decision (reasoning) and communicate the final decision (choice)(figure1).[12–14]

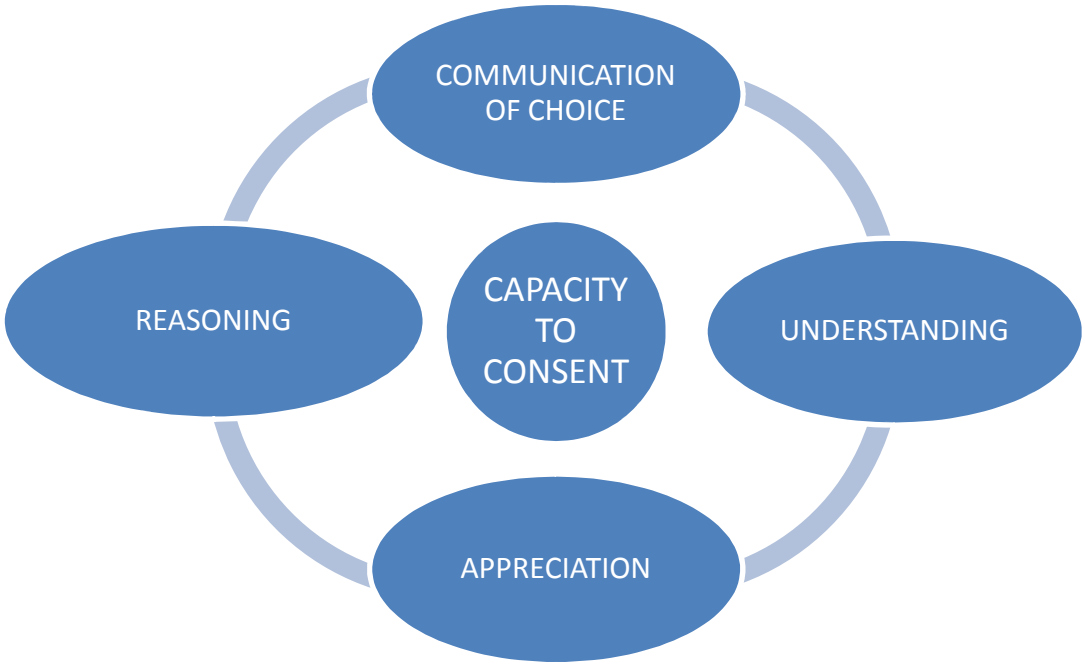


Figure 1. Representation of the domains of capacity to consent

Commenting upon the capacity to consent is needed so that, a person retains as much autonomy over his decisions as possible.[15,16]

Among many definitions of 'Autonomy', one definition was given by Miller in 1981. He defined 4 characters of autonomy, which are as follows[17]:-

a. Free action- It constitutes that, a person should be able to take a decision understandingly, by oneself and act according to their own will.

b. Authenticity – It constitutes that the act or decision should be in keeping with the patients' values, beliefs, and desires.

c. Effective deliberation- It constitutes that the person should be able to understand the situation, advantages and disadvantages of the possible solutions provided. He or she should be able to select the best possible solution with careful consideration of the pros and cons.

d. Moral reflection- It constitutes that the person should be able to independently re-evaluate the option chosen, the values and the risks associated with the decision.

Capacity is assessed clinically, by a psychiatrist, though not compulsorily. It can even be assessed by a physician.[15] The basic requirements to comment upon the capacity to consent is given as per the health care legislations of the concerned jurisdiction.[18]

The terms capacity and competence are often used interchangeably, however have different meanings.[15,19] Mental competence as defined by the ' Black law dictionary as, "having sufficient ability, possessing the requisite natural or legal qualification to take part in a given venture".[20] It is the degree of mental aptitude, legally needed to take decisions regarding specific issues. For e.g. consent to treatment.[21]It is legal terminology for capacity[16], and is determined by a legal body (courts, review boards).[12] It is said to be specific to the question or the task in consideration.[22]

Roth et al (1977), demonstrated five tests to examine competency, "evidencing a choice", "reasonable outcome of choice", "choice based on rational

Reasons", "ability to understand", and "actual understanding".[23] Based on previously mentioned tests by Roth, in 1982, Appelbaum and Roth, gave four legal standards. These are considered to be the functional abilities to test competency. They are: - expressing a choice, understanding the issues, reasoning regarding information provided and appreciation of the nature of the issue.[24]

Competence comprises of a few legal necessities, such as, capacity to understand and act in a reasonable manner[21,25], age of the person, jurisdiction and its laws regarding competence. When the issue of incompetence is taken up in the court, it is finally up to the appointed review panels or judge(s) to decide, if the person in question, is competent according to the legislated criteria. If found competent, their

stated wishes should be respected.[25] Competence is dichotomous. By law, a person is either said to be entitled or not entitled to, have their wishes respected.[16]

Mental capacity is said to be a continuous quality which is present to a greater or lesser extent in every individual.[16] Capacity is also considered to be specific to the task at hand and the time at which it is assessed. For e.g.: for a patient, who is getting admitted to the hospital to undergo a particular procedure, the capacity to consent for both, the admission and the procedure will have to be assessed separately, at different times.[26] Therefore, capacity is considered in relation to specific decisions like, capacity to consent to treatment[27], to consent to research especially for patients with depression, Alzheimer's dementia, intellectual disabilities[28–30], to exercise advance directive.[31]

Capacity is said to be variable. It varies with respect to the problem at hand. It is different for different problems; it may vary for the same problem when viewed over a period. Thus, capacity to consent requires frequent reviewing and periodic assessments.[32]

When the degree of complexity of the task at hand is considered, there is said to be a proportional increase in the degree of capacity required. Thus, capacity required for more complex tasks is more and has a greater impact on the life of the concerned individual.[16,33]This is called the 'balancing' approach'. Therefore, there is no fixed threshold at which capacity to consent can be adjudged as present or absent.[34] Capacity, as defined by this approach is a measure of either how much autonomy a person possesses, or how much importance should be given towards respecting the autonomy.[35] This type of dilemma is usually encountered when the patient's decision is not in keeping with the popular opinion or with what other people think to be in the patient's best interest.[36]

It is considered imperative that, before subjecting the patient to any diagnostic or therapeutic procedure, the treating doctor must inform them in detail about the same. It should be done in a simple language and as per the requirement by law and ethics, an informed consent should be taken.[37] If the patient has an intact capacity to consent, then the medical practitioner should respect the decision and it. If the doctor is unable to do so and goes against the decision, it translates into curtailing the right to liberty and right to choose and may end up being a legal issue.[11]

If the person is not able to come to a decision, which is in his or her best interest or is not able to communicate the same, the person is said to have an incapacitated state of mind. The decision should be taken by a proxy or a relative (nominated representative), thereby ensuring legal protection of the patient's rights.[26,38]

If a person is found to have impaired capacity to consent, the decision-making process for the person should either be in accordance with what would be best for the patient or the decision should be taken by someone else (substitute decision making by advance directive or court order). The decisions can also be taken in accordance with any prior advance directives (AD) or with the help of a nominated representative (NR).

HISTORICAL BACKGROUND

The concept of caring of persons with mental illness (PMI) in asylums, in India, was introduced by the British in the 19th century.[39] In 1912, The Indian Lunacy Act (ILA) came into existence to foresee the governance of these asylums, A central authority was appointed for the supervision of the same.[40] The main idea of asylum care was to protect people from unmanageable and violent patients who posed a threat to themselves and the society.[40,41]In the middle of the 20th century, United Nations

adopted the universal declaration of human rights, which led to change in the ILA.[40] According to the constitution of India, Article 21, Right to life and liberty, people can express their free will and take decisions on their own accord and should not be deprived of their life and liberty, unless proven otherwise by the law.[42,43] The Indian Lunacy Act, dealt with keeping patients with mental illnesses, in custody without their due consent. This led to the drafting of a new mental health bill in 1950, which was later passed as the Mental Health Act (MHA)(1987).[40,44] According to it, patients who refused admission to a psychiatric in patient set up, could be admitted against their will if the relative or a friend gave an application for the same and two psychiatrists after examining the patient deem the cause for admission as necessary (Chapter 4, section 19). It also mentions that the rights of the PMI should be respected and not be violated (chapter 8, section 81).[45] Like with ILA, there were a few issues noted within this act. Some of them were restriction of one's freedom, ability to take their own decisions and curtailment of one's liberty without being governed by a legal body. Another point of contention was that MHA gave the next of kin powers to take decisions on behalf of persons with mental illness. Hence, the PMI could be kept in the asylum against their consent, for a lifetime as and if the next of kin felt that it was in their best interest.[46]

In 2006, United Nations adopted the Convention on Rights of Persons with Disabilities (UNCRPD). India became a signatory after ratification by the Indian Parliament in 2008. This changed the regulations for people with disabilities (PWD) and the outlook towards them, from it being a social issue to being a human rights issue. It laid more emphasis on legal capacity, equality, and dignity for the people with disabilities, including mental disabilities. It enabled PWD to share legal capacity on an equal basis for all aspects of life.[46,47]

An amendment to the MHA was required. The laws for the governance of patients with psychiatric illness were required to be more accommodative of their rights.[48]For the betterment of mental health services, the government took steps by introducing the National Mental Health Policy in 2014 which was later enacted as the Mental Healthcare act (MHCA) 2017 with the support of all parties in both the houses of the Indian parliament on 29th May 2018.[1,49] Main focus for MHCA was mental healthcare delivery to people with Mental illness with greater focus on their rights, safeguarding and encouraging the preservation of the same.[2]This act seemed to be more liberal towards patients with mental illness and was also reforming in a few other ways. It considered the patient to be the centre of attention, had put more focus on their rights, especially when considering inpatient treatment given to them.[49] It provides patients with control of their own rights, enables them to take their own decisions and signing consent forms.[50]

According to section 4 of MHCA 2017, a PMI is to be considered to have intact ability (capacity) to take all decisions related to delivery of health care treatment, either in in-patient or an out-patient setup, until proven otherwise.[51,52] In other words, a Person with Mental Illness can give consent to various treatments amongst other things and should not be presumed to have reduced capacity to consent or have impaired judgement.[53]As mentioned by the Universal Declaration on Bioethics and Human Rights by UNESCO, in article 7, it states that if a person doesn't have the capacity to give consent regarding a particular decision, then as per the domestic laws, special arrangements such as opinion of a trusted relative (nominated representatives), advanced directives, second opinion can be made for such people to protect their rights.[26,54]

CONSENT

Informed Consent is process in which, a patient receives information regarding a particular treatment procedure. He or she should be able to understand it completely[55], measure the positives and negatives of their decision and take an informed decision by themselves. This should be in-keeping with their rights and decision making capacity.[56] The information given, should be adequate and important for them to choose whether they would want to go through with a particular treatment or not.[57] Information to be disclosed includes, proposed plan of treatment, risks and benefits of the same, alternate approaches available, if any. In other words, it gives a person, control over his decision of whether or not to give the doctor the authority to perform a healthcare related act on them[58]

The validity of consent is based on five of its constituents-

1. Voluntarism- It denotes the free will of the patient to take decisions. Patient should not be controlled, influenced or swayed by someone (persuasion) and should not be forced or manipulated (coercion).[58,59]Psychiatric patients are often at risk of being subjected to external influence by the doctor to accept a certain treatment. It can be reduced by the presence of family members or nominated representatives.[60]

2. Capacity- It is defined as the mental ability of the patient to understand the given information and act in their best interest according to their perception and acumen.[53]

3. Disclosure-It refers to divulging certain and adequate details about the treatment, which would be required by the patient to make an informed choice of whether to accept or deny it.[61]

4. Understanding- Refers to the ability of the patient to be able to grasp the meaning of the information shared. The patient should be able to attribute its importance, risks and benefits, to his condition.[62]

It can be a problem in patients who have difficulties assimilating and comprehending the information given. For e.g. In patients with acute agitation or with impaired mental functioning like in dementia.[6015]

5. Decision- It stands for the authority that the patient has, over whether to allow the doctor to implement the proposed treatment or not.[62]There can be a severe impairment in the ability to take decisions due to excessive anxiety states, Obsessive Compulsive Disorder or Generalised Anxiety Disorder. It can also be seen in psychotic illness such as, due to the presence of delusions , hallucinations, impaired reality orientation and lack of awareness of illness.[6015]

One of the difficulties to get informed consent from psychiatric patients is, regarding their capacity to give consent. It is not necessary that all persons with mental illness will have reduced capacity to give consent regarding treatment.[59]

CAPACITY ACCORDING TO VARIOUS JURISDICTIONS

INDIA: -

According to MHCA, 2017, Chapter 2, Clause 4, "mental illness and capacity to make mental healthcare and treatment decisions", any person, including PMI, is to be considered to have Capacity if, -

a. He or she can make sense of the information which is relevant to the decision-making process (understanding)
b. Can appreciate the consequences of accepting or refuting a decision. regarding treatment, admission, or personal assistance
c. Can communicate the decision, by verbal or nonverbal means such as expression, gestures etc.

The information that is provided should be in simple language or using, sign language or using audio-visual aids, which can be easily understood by the individual.

If the person fulfils the criteria for having intact capacity to consent, as mentioned above, any decision taken by the person should be respected. Even if the decision is inappropriate or not as per social norms, the person should not be deemed as having lack of capacity to consent to treatment.

According to chapter 12 of MHCA 2017, "admission, treatment and discharge", based on the status of capacity to consent to take treatment decisions, patients can be admitted as independent admissions or high support admissions.

Independent admissions are considered when a PMI desires admission and has intact capacity to consent to treatment and other decisions related to healthcare.High support admissions/ Supported admissions are considered when the illness of the PMI is of higher severity, has impaired capacity to consent and is a: -

a. Threat to self, has recently attempted or is threatening to inflict self-harm.
b. Threat to others, has recently harmed or been violent towards others, putting them in danger of serious harm.
c. Unable to take care of self to the extent that he might cause harm to self.[2]

Sections 86 (3), 89 (c), 90(c) and 94 deal with admissions of persons as independent or high support.

Section 86 (3): - Independent admissions. Individuals who request for admission out of their own free will, can understand the nature and need for admission and have intact capacity to consent to mental healthcare and treatment. This decision should be made either without any support or with minimal support from others. They should not be influenced or be under any undue pressure from anyone to do the same. Such

individuals can be admitted under this section. Nominated representatives and advanced directives cannot play a role in decisions under this section.

If a patient is unable to understand the nature and need for treatment, the effects of accepting or refuting the proposed procedure and requires a high level of support to take decisions is admitted as supported admissions.

Section 89 (c): - Supported admissions for up to 30 days. Patients with mental illness with severity matching the criteria mentioned before for admitting patients with high support needs are admitted under this section. Before admitting, they should be examined by a psychiatrist and a mental health professional or a medical practitioner. Both should independently conclude that there is a need for admission based on examination and relevant information provided by others. Patients with impaired capacity to consent only can be admitted under these high support sections (section 89(c) and 90 (c)).

The psychiatrist or the head of the mental health establishment has to report to the respective mental health review boards (MHRB) within three days of admitting a female or a minor and within seven days of admission of a person who is not aforementioned. play a role in admission and treatment related decisions of the person.

In case of any issues with the decision of the medical officer or the head of the establishment, the patient himself, the NR or a member of a non-government organisation with patient's consent can write an application to the MHRB to review the decision. The board will process the complaint and respond within seven days after receiving the complaint.

Section 90 (c): - supported admissions for more than 30 days. If the medical officer feels that the patient requires further treatment beyond the thirty-day period or once

discharged after being admitted under section 89, needs re-admission within seven days, the patient, after due procedure is admitted under this section. The NR is required to give an application for continuation of in-patient stay for the patient. It is only after being examined by two independent psychiatrists in the past seven days and they independently conclude based on their examination that the patient has consistently over time fulfilled the criteria for high support admission, the admission can continue.

The MHRB must be informed within a period of seven days of such an admission. During the board's evaluation, the need for institutional care and the lack of options for a less restrictive care in the community are considered. Under this section the patient is admitted for 90 days in the first instance. If the duration of in patient stay needs to be extended beyond 90 days, if the application is considered by the board, the patient can be admitted for 120 days in the first instance and 180 days each time an extension for the stay is needed. Formal capacity assessment needs to be done every two weeks for such patients.

The treatment in sections 89 (c) and 90 (c) is initiated only after considering advanced directive or after taking consent from the nominated representatives if any.

Section 94: Emergency treatment. If any PMI is at an immediate risk of death or irreversible harm to health, inflicting serious harm to himself and/or causing serious damage to his property or that belonging to others. The above should be a consequence of his/her mental illness, can be provided immediate care. The care includes any medical or psychiatric treatment, to be given after due consent from NR. This section also includes transportation of the PMI to the nearby mental health establishment. This section is valid till 72 hours or till completion of the assessment by the psychiatrist.[1,2,26,63]

IN OTHER COUNTRIES: -

In countries like in Canada, Australia New Zealand, United Kingdom and USA, the capacity assessment laws try to maintain a balance between the individual's rights and autonomy and safeguarding the PMI and other people living in the community from any harm.

Patient previously treated in in-patient setting, in dire need of continued treatment and a risk for refusing treatment, once they are out in the community are treated by a 'compulsory community treatment order'.[64]

UNITED KINGDOM

Capacity to consent is governed by the Mental Capacity Act, 2005. It was made to protect people with mental illness especially those who lack capacity to consent.

It has 5 principles which are as follows-

1. Intact capacity is to be assumed for every individual. The diagnosis, behavioural pattern and subjective view of the individual shouldn't lead to a bias towards presence of incapacity.
2. Decision making ability of the individual should be enhanced in all possible ways before commenting impaired capacity to consent to treatment. Use of simple language, sign language, interpreters, adequate time for assessment should be done. Repeated or periodic assessments of capacity should be done in cases with fluctuating nature of capacity is noted.
3. To comment upon the status of capacity to consent, it is the process taken to reach the decision and not the final decision which serves as the determinant.
4. Best interest principle: -for people not having the capacity to consent, the decision taken on their behalf should be in their best interests.

5. Decisions taken on their behalf shouldn't be restrictive towards the basic rights and autonomy of the concerned persons. [65]

AUSTRALIA

Each of the six states has their own laws regarding treatment of patients with mental illness. There is mental health act 1994 (Australian Capital Territory), 1996(Western Australia), 2013(Tasmania), 2014 (Victoria) and so on.

According to the act, a person is said to lack capacity, if at a particular time, due to underlying impairment in the functioning of the mind or brain, the person is not able to make a decision for him or herself.

Patient is considered to have impaired decision making ability if, the person has problems with understanding and retaining the information provided, weighing the information provided in the decision making process and clearly communicate the decision verbally or non-verbally.[66]

In order to treat patients with psychiatric illness, who are in need of it but deny the same, the capacity and the risk related to his illness, both are taken into account. To treat against the will or not is determined by considering the risk and harm posed by the PMI to the community.[67]

CANADA

The 10 provinces and 3 territories have their own mental health laws and services. There is a total of 13 mental health laws in Canada. These laws mostly are more accepting of the voluntary admissions. For the involuntary admissions or community treatments, three elements should be applied. They are: - committal process, committal criteria and the rights procedures.

Committal process- it is the process which is undertaken to take the decision of detaining the patient in a mental health care unit. The patient is reviewed by 2 clinicians, and the need for detention should be decided by agreed upon by one of them.

Communal criteria- it encompasses the definition of mental disorder i.e a person with a defined mental disorder only can be involuntarily be admitted. It also encompasses the assessment of the harm the patient might pose to self or the community and the level of deterioration the patient might face.

Rights procedures- after the involuntary admission, the patients are made aware of their rights like, right to detention, right to consult a lawyer or repeal in quasi-judicial courts for release.[68]

Therefore, in Canada, it is the rights of the persons with mental illness which are always considered first, irrespective of the chance of serious harm the patient possess.[67]

CAUSES OF INCAPACITY

Impairment in capacity to consent for decisions are mostly seen in patients found in the emergency room, intensive care units, medical, surgical or psychiatric in-patient departments.[14]

The causes for incapacity in hospitals can be considered as:- medical and psychiatric.

Medical causes

- Conditions causing periodic fluctuations in capacity such as, unconsciousness, confusion, pain, fatigue, drugs, are amongst a few broad causes of lack of capacity.[69]
- Conditions like stroke, depending upon the size and location of the thrombus or bleed, might cause impairments in capacity to a variable degree.[70] Some patients

might have impairments in the decision making capacity due to the underlying conditions. These include subdural hematomas, brain tumours, and septic encephalopathy. A few other causes like high fever, reduced oxygen saturation, uraemia, increased sedation, which in turn might affect the patient's ability to think clearly and give consent.[71–73] In such cases the capacity might improve once the underlying condition is taken care of.[71]

- Amongst other medical causes, life threatening illnesses, stress of the same, hospital visit at that time, can limit, if not completely impair the patients capacity to consent to treatment.[74]

Psychiatric causes

Considering psychiatric causes of incapacity, nearly 50% of the patients with acute schizophrenia and bipolar affective disorder are said to have either complete incapacity or at least impairments in one of the aspects determining capacity. Around 20-25% patients, with a diagnosis of depressive disorder are found to have impaired capacity to consent.[5,6,75]

Patients with reduced mental acuity and lifelong disability such as mental retardation are also said to have impaired capacity to consent. There are certain conditions in which the loss of capacity is correlated with the onset of the disease process. For e.g. head injury, onset of dementia.[69]

Conditions affecting the higher mental functions and by extension, the decision-making process, also entails impaired capacity to consent. For e.g. patients with dementia are found to have lack of treatment related decision-making capacity. As the severity of dementia increases, the degree of impairment in capacity also increases.[76]Capacity might also change due to the fluctuating level of the underlying illness. This is more commonly seen in patients, who are in delirium, patients with

mild dementia and in those suffering from schizophrenia.[71]At times, a person's mental state can also affect the decision making at that particular time. For e.g. when a person is really anxious or fearful, it can cause problems with understanding and logical reasoning, of the information provided.[19]

Psychiatric, neuropsychiatric conditions can affect certain domains of capacity (understanding, appreciation, reasoning, or expression of choice), thereby affecting the capacity to consent. For e.g. disorders causing impairment in communication of the choice such as, those with stupor, mutism, impaired verbalisation, or patients in an ambivalence (indecisive) state. Patients with psychotic disorders, due to the presence of thought phenomenon (thought echo, thought broadcast or withdrawal) or delusions can also have impairments in understanding or communicating a choice. Thereby, causing impairment capacity to consent.[5,12,77]

Disorders like chronic schizophrenia, severe depression, dementia or intellectual disability can cause problems with understanding of information and thus, with the capacity to consent.[5,77–79]Presence of a persecutory or a grandiose delusion can cause difficulty in understanding the risks and benefits of the treatment options given to the patients. Conditions like dementia, intellectual disability, usually have a concrete abstraction and poor problem-solving abilities. This can cause impairments with rational manipulation of the information i.e. reasoning domain of capacity.[80]

PREDICTORS OF INCAPACITY

There are various factors which influence capacity to consent to treatment. Some of them also serve as predictors of incapacity.

Insight as defined by Amador and David (1998), defined it as a multi-faceted concept. It includes, a) being aware of one's disorder and the need for treatment, b)

understanding the social implications of the disorder, c) being aware of specific signs and symptoms of the disorder, their attribution to the disorder.[81] Cairns et al (2005), in his study, to find the prevalence and predictors of incapacity in psychiatric patients, patients who had better insight scores, were less likely found to have incapacity to take decisions. They also hypothesized that, patients with psychosis or mania, due to their lack of insight into their illness, can be associated with, as having impaired capacity to consent.[6]

Dunn et al (2007), found a significant correlation between the scores on Birschwood Insight scale (level of insight) and scores on MacArthur Competence assessment scale (capacity assessment scores).[82]

Wong et al (2005), in his study to assess decision making capacity of the inpatients suffering from schizophrenia, found a strong correlation between the insight and judgement domain of schizophrenia and MacCAT-T scores.[83]

Thus, awareness of one's own disorder is closely linked to the judgement of the consequences of the treatment advised (appreciation, reasoning domains), also with, giving a preference (expression of choice domain).[4]Lack of insight is considered to have a strong association to predict incapacity but it is not indicative of the same.[6]

Abnormalities in neuropsychological tests also serve as predictors towards incapacity. Scores less than 19 on mini-mental state examination (MMSE) is a predictor of incapacity, while, scores above 23 predict higher chances of retention of capacity.[84,85]

Marrodán et al (2018), in his study to find the prevalence of incapacity in patients with normal MMSE scores, found that, patients with impaired capacity to consent, had below threshold MMSE scores. They also found that, patients with cognitive impairments, had poor scores in understanding and reasoning domains of MacCAT.[86–88]

Raymont et al (2004), found that MMSE scores suggestive of cognitive impairments are suggestive of mental incapacity and older age groups.[89]Marrodán et al (2014), found a statistically significant difference ($p < 0.0001$) between MMSE scores of patients with capacity and with impaired capacity. Patients with impaired capacity had lower MMSE scores.[90]Bilanakis et al (2014) found a significant positive correlation ($p<0.0001$) between MMSE scores and reasoning scores on MacCAT-T.[87]

Amongst other predictors, a person's personality, level of education, subjective mood, might have a bearing on the understanding and appreciation of various issues associated with a decision.[91]

Presence of positive symptoms (hallucinations, delusions), negative symptoms, unusual thought content, disorganised speech and thought, high support admission, treatment refusal, also have a strong predictive value for impaired capacity to consent, especially in patients with chronic mental illness.[92]

NEED FOR FORMAL CAPACITY ASSESSMENT

Usually it is the treating doctor who takes a call regarding the patient's capacity to consent for various treatments and procedures. Assessment of a patent's decision making capacity is an integral part of the initial examination of the patient and also of examinations thereafter.[93]

It is the process through which a particular decision is reached, and not the decision taken that guides the need for a formal assessment of capacity.[94] Finding the person with a lack of decision making capacity causes an ethical dilemma, whether to respect the patient's rights and autonomy, or to take necessary steps to protect the person. One should also keep in mind, what a legally appropriate step in such conditions would be.[69]

For a patient with intact capacity, who refuses a given treatment which might be much needed for him, regarding him or her, as not having the capacity to consent, and going against their wishes, will lead to autonomy violation and forcing of the treatment. If the patient lacks the capacity to consent, accepts the treatment without rational manipulation of the information and despite it, is cleared to have decision making capacity, this will mean that the patient is not protected legally.[91]

There are often subtle signs of impaired capacity like cognitive issues, which might be easily missed. Thus, a formal assessment helps in maintaining the balance between respecting the rights of an individual and protecting him or her from harm.[12]

Bellhouse et al (2014), studied the decision-making capacity related to treatment decisions in a psychiatric patient population. He found that only 20% patients had impaired capacity to consent. He also mentioned that the presence of psychosis is not always associated with incapacity. 6 out of 9 patients in his study had the capacity to consent to treatment.[95]Capdevielle et al (2009),in his study found that, not all patients with schizophrenia have impaired capacity to make decisions, it is only a specific subset of schizophrenics which have incapacity towards decision making and thus presuming incapacity for such patients adds to the stigma and deprivation of the rights.[4]

In another study done by Raymont et al (2004), regarding the prevalence of mental incapacity in acute medical inpatients, they found that only 24 % of individuals had impairment in capacity to consent, when subjected to a clinical interview. However, upon formal assessment done using MacCAT-T, 31% were found to be having impaired capacity to consent. They, in conclusion, also mentioned that medical incapacity is a common finding in the above-mentioned population and is very easily missed. Thus, the need for a formal assessment arises.[89]

Elzakkers et al (2018), studied the prevalence of decision-making capacity for treatment in patients with anorexia nervosa. The assessment was done by two methods. First, by a clinical interview conducted by a psychiatrist, second assessment was done using a formal capacity assessment tool (MacCAT-T). Both the assessments judged around one-third of the patients as having impaired capacity to consent. This should good agreement between the two measures. However, 13 patients who were adjudged to have intact capacity to consent clinically, on formal assessment were found to have impaired capacity. 11 out of 23 patients, who were adjudged to have impaired capacity clinically, upon assessment, were found to have intact capacity.[96]

The need for assessment most commonly arises when one needs to decide regarding treatment, self-care capacity[97], refusal to accept treatment.[98]

Formal assessment of capacity serves as a legal buffer, especially when the status of capacity is not clear and the patient might be at a risk of violation of his rights.[99,100] Assessment of capacity becomes even more important when the issue of marginal competency arises. Marginal competency, is when competency cannot be clearly judged in a dichotomous form and might cause misclassification of the patient's capacity.[91,101]

Any person with mental illness is vulnerable various risks, manipulations, and harm via coercion by others or family members. This becomes even more important when there is lack of insight into one's illness. Hence assessing capacity to consent becomes a must, to legally safeguard the person.[26]

CAPACITY ASSESSMENT

Assessment of capacity to consent should be conducted by someone who is familiar with mental status examination, abilities involved in competence assessment, implications of the patient's disease and the treatment advised.[93]

According to the MHCA 2017, if a patient is admitted under section 89 (c), a formal assessment of capacity to consent must be done every 7 days. For patients admitted under section 90 (c), a formal capacity assessment must be done every 14 days. It is assessed by mental health practitioner or a psychiatrist.[2,26]

The assessment done can be challenged by the patient himself, the NR or anyone from an NGO on patient's behalf after taking due consent. The appeal will have to be made to the MHRB to review the decision which will respond within seven days. The final decision of the MHRB will have to be agreed upon by both the parties involved. [2]

APPROACHES TO CAPACITY ASSESSMENT

To mark a threshold to determine capacity to consent, the criterions which determine capacity should be adequate. They should not be too restrictive i.e. too harsh a criterion which would curb the patient's autonomy. They shouldn't also be too lenient, that they fail to protect the persons with mental illness.[23]

There are 3 broad approaches towards capacity assessment[102,103]:-

1. Outcome approach: It takes into account the consequence of the decision taken. It lays more focus on the final decision rather than the process of reaching the decision. For e.g. if the decision taken, is not in keeping with the most popular one, or not according to what the treatment provider deems as fit, the patient is said to have a lack of decision-making capacity.

Drawback of such an approach is that, it belittles one's autonomy and self-determination.[103,104]

2. Status approach: The status of capacity is predetermined by the presence of certain characteristics or his or her representation in a particular group. The characteristic could be the diagnosis of the individual or the mental age of the patient.

   It considers the status of the capacity and the decision-making process to be common for all those who belong to the same group. For e.g. patients with schizophrenia are considered to have poor decision making capacity.[77,105]

3. Functional approach: This approach is similar to the one proposed by Appelbaum and Grisso. It takes into consideration, a person's understanding of the illness and treatment, appreciating the need for the same, rationally manipulating the information and expressing a choic.[12–14] It also focuses on the knowledge, skills and abilities which would be required for the decision making process and the legal parameters for the same.[106]

It advocates that, if a patient is found to have impairment in capacity to consent, efforts to try and enhance the decision making should be made. It can be done by either educating the patient more about the illness, correcting any underlying cause for incapacity, providing information in a simple language, details should be given in smaller amounts or diagrammatic representations for the same should be used.[5,107]

This approach also comes with a few problems.

a. It is time consuming
b. It is task specific. Assessments should be repeated whenever a new decision is to be undertaken.[26,103]

c. There is no uniformity in capacity assessment laws. There is no consensus regarding rules which govern the capacity to consent. Different jurisdictions have different legal standards.[106,108]

To determine capacity, instead of following any single approach, a combination is said to be helpful. For e.g. a combination of functional and the outcome approach would be helpful. It would help create a balance between autonomy and harm reduction.[16,34]

ABIITIES RELEVANT FOR DECISION MAKING AND ASSESSMENT OF CAPACITY TO CONSENT

The legal standards to determine competence to make decisions differ from one jurisdiction to another. There are some abilities which remain central to the process of determination of decision-making capacity from both a legal and clinical perspective. There are 4 abilities which are said to be central to the process of decision making capacity and also to the legal concept of competence, namely- [69,93]

1. Communication of a clear choice
2. Understanding and retaining the information provided
3. Reasoning and rational manipulation of the provided information
4. Appreciating the situation and the consequences

COMMUNICATING A CHOICE

The ability to communicate a choice is considered to be almost a universal sign of competence and capacity.[24] It is regarded as one of the easiest to assess, it only requires an answer regarding the decision under consideration.[3,23]After due informed

consent, patient is asked as to what his preferred choice is. The stability of the decision can be tested by asking the question again.[93]When considered alone, this standard is not sufficient to judge presence or absence of capacity to consent. It does not reflect the due process of decision making. Doesn't guarantee if the repercussions of the decision making were taken into account or whether the patient will be protected from harm or not.[69]

UNDERSTANDING AND RETAINING THE INFORMATION PROVIDED

This ability is more often mentioned in various capacity laws. According to this, if a person is unable to understand the information provided regarding the treatment, they do not possess the capacity to make an informed decision regarding the same.[93]The treatment information should be provided in a simple and layman language. Even if the person is grossly able to understand the treatment details, the capacity is said to be intact.[109] Another aspect of this domain is retention of information. The patient should be able to summarize and restate the information, in his own words (paraphrase). If the patient is able to paraphrase, this entails that retention and thus, understanding domains are intact.

REASONING AND RATIONAL MANIPULATION OF THE INFORMATION

It is the ability to use a logical process to reach a decision. It involves weighing the information, comparing the risks and benefits of the treatment options given. The consistency of the logic behind the final decision should be maintained throughout the process of reaching the decision, as this process is concerned with chain of reasoning attached with the decisions.[5,93]It is not the final decision that matters, rather the emphasis should be on the process taken to reach the decision. Final decision can be irrational or unconventional, it shouldn't be a part of a

delusional belief or current illness.[93] The unconventionality of the decision can be explained by it being a rational product of the person's culture and underlying beliefs.[110]

The problems associated with this ability is that, it is difficult to assess rationality without considering the outcome of the decision.[69]

APPRECIATING THE SITUATION AND THE CONSEQUENCES

According to Faden and Beauchamp, "one can understand what one is told without understanding the specific implications it carries for their future".[58,93] Appreciation is the ability in which the patients with intact comprehension should be able to recognise the significance of the information for them.[93] It requires the person to recognise that they have a disorder and the given treatment options might be helpful.[69] To assess this domain patient should answer regarding the presence of illness as disclosed by the doctor, consequence of accepting or refusing treatment and probability of each of the consequences. This domain only assess the extent to which the person attaches a personal significance to the information provided.[69,93]

The 4 legal criterions can be evaluated as follows(the following has been adopted from an article by Paul.s. Appelbaum) [12]:

ABILITY	GOAL/ REQUIREMENT	METHOD OF ASSESSMENT	RELAVANCE
UNDERSTANDING	To be able to comprehend the information regarding one's own illness	Patient is asked to paraphrase the information regarding disease and/or treatment including the risks and benefits of the treatment.	Information given includes nature of the condition, details regarding proposed treatment, benefits and risks of treatment and alternatives approaches.
APPRECIATION	Patient should be able to acknowledge the presence of the disorder and the need of proposed treatment. Patient should be able to attribute the information provided to self.	Patient is asked regarding his thoughts on the doctors disclosure regarding the diagnosis and clinical features, his views of the probable benefits of the treatments advised.	Lack of insight is one of the most important factors governing this domain and hence gives us a major idea regarding capacity in most cases. Delusion of persecution, delusion of grandeur can be causes of impairments.
REASONING AND RATIONAL MANIPULATION OF THE PROVIDED INFORMATION	The patient should be able to manipulate the information mentally in such a way that before coming to a final decision, he or she is able to rationalise how the treatment would affect various domains of life.	Patient is asked to draw comparison between the different treatment options, consequences of choosing a particular option and state clear reasons for the chosen option.	It mainly focuses on how the person was able to reach the decision. The final decision however unconventional and irrational, should not be taken into consideration till the time the process followed was not governed by cognitive factors and thought abnormalities like delusions etc.
COMMUNICATING A CHOICE	To indicate a clear and preferred choice of treatment.	Patient is asked to state his choice or more preferred mode of treatment.	Unable to give a clear choice or frequent changes in decision are a marker for incapacity.

METHODS OF CAPACITY ASSESSMENT

A formal assessment of capacity is mostly needed when the marginal capacity is comes into picture. To make sure that the method used is reliable and fair, it should be psychometrically appropriate and sound. To increase its validity, the appropriate assessment should be applied keeping in mind the socio-cultural background and the nature of patient's illness. To keep the test independent and away from bias that might occur due to the doctor-patient relationship, third party assessors like mental health tribunal, second opinions, volunteer workers can be helpful.[91]

There are various capacity assessment tools which exist. They are mostly structured or semi-structured tools. There are few which are self-administered. For e.g. two-part consent forms, they only assess the understanding domain of capacity and are followed up by questions from the assessor. Some tools assessed all the four abilities required for legal competency, for e.g. MacCAT-T, Competency Interview Schedule (CIS), Competency To Consent To Treatment Instrument (CCTI), Assessment Of Consent Capacity For Treatment (ACT). Tools Like, Direct Assessment of Decision-Making Capacity (DADMC), measures only understanding and reasoning, Ontario competency questionnaire (OCQ), measures only understanding and appreciation or Hopemont capacity assessment interview (HCAI), measures understanding, appreciation and communicating a choice.

Some of these tools make use of pre-determined case vignettes such as ACT, HCAI, CCTI, DADMC. While others make use of the patient's actual treatment details like MacCAT-T, CIS, Competency assessment interview (CAI), to assess the various domains of capacity. Tools like MacCAT-T, DADMC, Structured interview for competency/incompetency assessment testing and ranking inventory (SICIATRI), HCAI require prior training and education.[111,112]

Advantages of using semi-structured scales: -

1. It gives criteria which can be put to test.
2. Helps demarcate the status of capacity and incapacity which in turn would make the process of consent taking unambiguous and transparent.
3. Takes into account and puts to rest the differences and idiosyncrasies between the clinicians regarding one's competency.
4. It is relatively easy to train someone to conduct a structural interview.[91]

MacARTHUR COMPETENCY ASSESSMENT TOOL-TREATMENT (MacCAT-T)

There have been several concepts regarding the abilities essential for legal competency. In recent years, there has been a consensus upon the same which resulted in agreement for four major abilities:- understanding the information, rationally manipulating the information, appreciating the illness and need for treatment, expressing a choice.[3,93,106] Keeping the same in mind, Grisso and Appelbaum in 1995, designed the MacArthur treatment competence research instrument.[3,113] This instrument, even though helpful for research purposes, was not very useful in clinical setting. It took 60-90 minutes to administer and couldn't be drafted according to the patients symptoms or treatment.[114]

Based on the instrument mentioned above, Grisso, Appelbaum and Hill-Fotouhi, in 1997, developed the MacArthur Competency Assessment tool-Treatment.[115] It is a semi-structured interview, takes around 15-20 minutes to administer. It makes use of the patient's own clinical and treatment details, making it more reliable in clinical setting.[115,116]

MacArthur Competency Assessment for Treatment (MacCAT-T) is a semi-structured interview and one of the most widely used tool to assess the capacity to take decisions regarding treatment[87,117]. This tool was developed by Thomas Grisso

and Paul S. Applebaum[118]. The time needed for the use of this tool is around 15-20 minutes. [114]

It comprises of 2 components – Structural and functional.

The structural component deals with what kind of disorder is present, whether psychiatric or neurological.

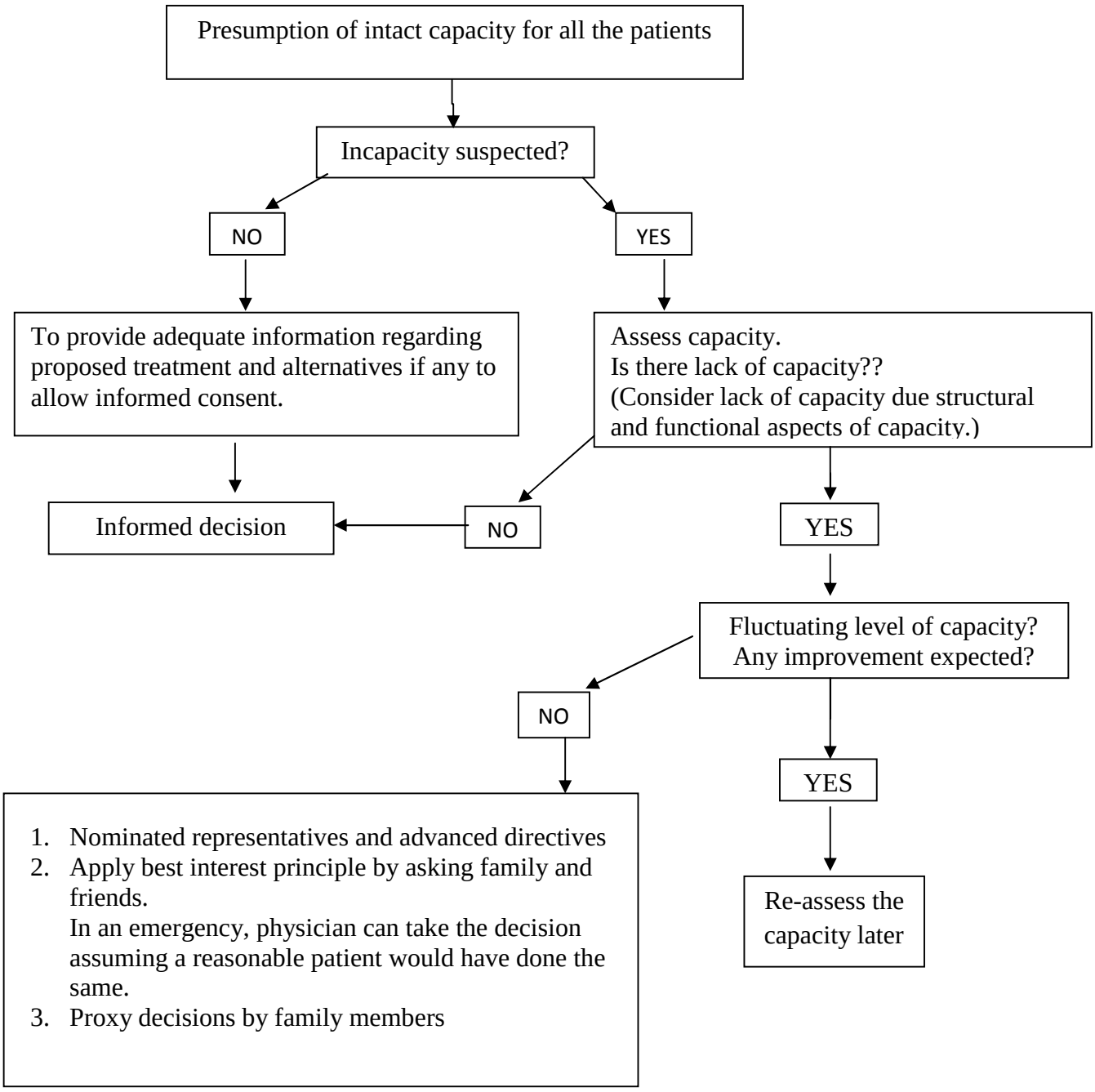
The functional component deals with decision making and its process. It assesses the four legal criterions mentioned by Appelbaum and Roth (1982) i.e. understanding the information provided, retention of the given information, weighing risks and benefits rationally, communicating a choice.[26]

The MacCAT-T interview begins with divulging the patient's diagnosis and nature of the disorder. During the process of the interview, the proposed treatment and alternatives, risks and benefits associated with them are also disclosed. Patient is asked regarding the preferred treatment choice, and the reasons of choosing it and consequences associated.[114]

The four domains (understanding, appreciation, reasoning, and expression of choice) are rated according to the quality of responses from 0 to 2, wherein, 0- inadequate response, 1- partially adequate, 2- adequate response. The domains have summary scores, understanding (0-6), appreciation (0-4), reasoning (0-8) and expression of choice (0-2). The tool doesn't give a total score.[119] The scores hint towards the degree of impairments in the respective abilities. It does not give a dichotomous result of presence or absence of the capacity to consent to treatment. The results of the assessments should be considered in combination with the clinical assessment These ratings are not representative of legal competence or incompetence,.[117,118]

MacCAT-T does not provide a minimum score to determine if the capacity to consent is intact or impaired. Scores which are below the 50% range for the four legal criteria indicate impairments in the respective domains, which hint towards incapacity.[120]

FLOW CHART DEPICTING STEPS TOWARDS CAPACITY ASSESSMENT (The following schema has been adopted from an article by Nicholson et al) [65]



PSYCHOSIS

As defined by Diagnostic and Statistical Manual of Mental Disorders, fifth edition (DSM-V), psychosis is a state with gross reality impairment with patients having no insight into their illness. It causes an inability in carrying out daily routine activities. The abnormalities present might be delusions, hallucinations, disorganisation of speech and thought, abnormality in motor behaviour or gross disorganisation and negative symptoms.[121]

According to International Classification of Diseases (ICD-10), it is defined as presence of hallucinations, delusions, or extremes of behaviour patterns (gross excitement, marked retardation or catatonia).

These disorders are classified from ICD F20 to F29. It includes diseases like[122]:-

1. Schizophrenia and its various subtypes (F20.0-20.9),
2. Schizotypal disorder (F21),
3. Persistent Delusional Disorder (F22),
4. Acute and Transient Psychotic disorders (F23.0-23.9),
5. Induced delusional disorder(F24),
6. Schizoaffective disorders (F25.0-25.9),
7. Other nonorganic psychotic disorders (F28),
8. Unspecified nonorganic psychosis (F29).

As per NMHS 2015-16, psychosis had a lifetime prevalence of 1.4 % and a current prevalence of 0.5%. Incidence of psychotic illnesses was higher in males (0.5%) as compared to females (0.4%). People in the age group of 40-49 had a prevalence of 0.6%.[7]

The severity of psychosis can be measured by rating scales such as Brief Psychiatric Rating Scale (BPRS) [123]and for schizophrenia; Positive and Negative

Syndrome scale (PANSS)[124], Scale for Assessment of Positive Symptoms(SAPS)[125], Scale for Assessment of Negative Symptoms(SANS).[126]

BRIEF PSYCHIATRIC RATING SCALE

It is used for a quick assessment of the psychopathology and change in the patient's clinical status. Along with helping in assessing the treatment change in patients, it also gives a comprehensive view of the psychopathology.[123] Developed by Overall and Gorhom in 1962, initially it was a 16- item scale. It was later changed to 18-item and further to 24-item scale in order to make it more sensitive towards psychotic and affective disorders.[123,127]

Hedlund and Vieweg (1980), identified four symptom clusters, which had three symptoms each. 12 of 24 symptoms were not grouped in any cluster. The four symptom clusters included are:- Psychoticism cluster (hallucinations, unusual thought content, conceptual disorganization), Hostility cluster (suspiciousness, uncooperativeness, hostility), Depression cluster (anxiety, depression, guilt), withdrawal cluster (motor retardation, blunted affect, emotional withdrawal).[128]

In their study to correlate BPRS scores with symptom severity using CGI scores, Leucht et al (2008), concluded that a score of 31 on BPRS, corresponds to 'mildly ill', BPRS score of 41, corresponds to 'moderately ill' and a score of 53 corresponds to 'markedly ill'.[129]

RELATIONSHIP BETWEEN PSYCHOSIS AND DECISION-MAKING CAPACITY

A mere formal diagnosis of a psychiatric illness does not directly correlate with impairments in capacity to consent to treatment. Lepping et al (2015), conducted a review to estimate the prevalence of incapacity to consent to treatment or admission,

amongst patients in different settings. They found that 45% of the patients admitted to the psychiatric ward had incapacity to consent and 35 % patients admitted to medical wards were found to have incapacity to consent. Thus, psychiatric inpatients don't necessarily have poor decision making abilities.[130]

There are specific clinical characteristics which are found to be associated with impairments in overall capacity to consent or in a few sub domains.[88] The most common factors associated are marked excitement[131], cognitive impairments[132] lack of insight[6], negative symptoms[133].

It was observed in the Clinical Antipsychotic Trials of Antipsychotic Effectiveness (CATIE) study (1999-2000) that, as the duration of illness progressed amongst patients with schizophrenia over the 18 month period, 56 % had stable MacCAT scores, 20% had improvement in the scores while 24% had deteriorating scores.[130,133]

According to Kovnick et al, Palmer et al and Moser et al, decision making capacity is strongly correlated with the negative symptom domain.[134–136]

Howe et al, mentioned that there is an inverse correlation between decision making capacity and positive symptom factors mainly involving cognition such as attention, abstraction difficulty and conceptual disorganisation.[131]

In a study by Cairns et al (2005), to assess the prevalence of mental incapacity in psychiatric in-patients to make treatment related decisions using MacCAT-T scale, it was found that around 44-60 % patients with psychosis lacked capacity related to treatment decisions. 50 % patients with an acute episode of schizophrenia had an impairment in at least one of the functional capacity domains as compared to 20-25% patients with depression had impairments with the same.[6]

Fernandez et al (2017), in his study regarding the relationship between changes in mental capacity, symptoms and functioning in patients with psychosis, found that 37.5% psychotic patients had incapacity to consent when admitted which eventually improved upon treatment.[137]

Jeste et al (2006), in their review article regarding, magnitude of impairment in decisional capacity in people with schizophrenia when compared with controls stated around 10-52% of schizophrenics had impairment in decision making capacity as compared 0-18% in non-psychiatric controls.[134]

Grisso et al (1997), in their study to find out the proportion of individuals with psychiatric and medical illness with incapacity to make decisions in relation to each of the legal standards for determining competence to consent to treatment, found that schizophrenic patients had significantly poorer scores when compared with patients with depression.

There is a subgroup of schizophrenic patients who, despite having an acute episode were at par compared to general population when the scores were considered. They also stated that 28 % patients with a diagnosis of schizophrenia and schizoaffective disorder had impairments in understanding, 24% and 22.7% individuals had impaired reasoning and appreciation on MacCAT-T scale, respectively. 25 % of schizophrenics overall, had impairments in at least impairment in one measure.[138]

MATERIALS AND METHODS

The study was designed as a cross-sectional study, aimed at assessing the capacity to consent to treatment in patients with functional psychosis, admitted to the psychiatric in-patient facility. The study was conducted at the in-patient unit of Department of Psychiatry at KLE's Dr. Prabhakar Kore Charitable Hospital, Nehru Nagar, Belagavi. Data collection took place between 1st January 2019 and 31st December 2019. Patients were recruited using purposive sampling. The source of the sample were the patients who were admitted in the psychiatry ward with a diagnosis of psychosis

Sample size

A total of 100 patients with a diagnosis of psychosis according to ICD-10 DCR were taken up for the study.

Inclusion Criteria

1. Age 18 years and above.
2. Patients admitted in the in-patient unit with an ICD-10 DCR diagnosis of psychosis (ICD F20.0-29.0).

Exclusion Criteria

1. Patients suffering from organic illness.

2. Patients with substance abuse and dependence who come in a state of delirium or complicated withdrawal.

3. Patients with diagnosed Mental retardation.

Procedure

The patients and attendants were explained regarding the study and its implications. A written informed consent from the patients was taken in their own vernacular language.

Patients' who were admitted with in a catatonic state or with extreme agitation were considered to have impaired capacity as they had impaired communication and understanding.

On receiving the consent to participate in the study, the patient was interviewed, and the diagnosis was confirmed with the help of a senior faculty. Once the diagnosis of psychosis was confirmed, the patient was subjected to a formal assessment of capacity to consent to treatment within 24 hours of admission using the MacArthur Competence as Assessment Tool- Treatment (MacCAT-T). 18- Item Brief Psychiatric Rating Scale (BPRS) and Beck's Insight tool were applied to assess the severity of illness and the level of insight, respectively. All interviews and rating scales were applied by the primary investigator after undergoing training and supervision to ensure valid and reliable assessments.

For the study, capacity to consent was said to be impaired when the patients had 50% or less scores on any one of the sub-domains of MacCAT-T, which is a standard practice as mentioned in the MacCAT-T manual and as used by Fernandez et al in their study to assess the recovery factors associated with the decision-making capacity of patients with psychosis.[120,139]

Tools

1. **MacArthur Competency Assessment Tool – Treatment (MacCAT-T)**

It is a semi-structured interview, used for the assessment of capacity to make treatment decisions. It requires 15-20 minutes to administer. It assesses the 4 domains associated with assessment of capacity to consent, namely, understanding, appreciation, reasoning, and expression of choice. It helps the clinician through a disclosure of patients' own disorders and treatments. It does not provide a composite score or a binary result of presence or absence of capacity but assists in finding out the domains with impairment.Understanding is tested by providing diagnosis and treatment related information to the patient and the patient's ability to paraphrase the same. The score ranges from 0 to6.

Appreciation is tested by asking the patient if the disclosed information regarding diagnosis applies to him/her and if the treatment would be of any benefit or not. The score ranges from 0 to 4.Reasoning is tested by asking the patient the possible consequences of the choice made and comparing the choice with other modalities. The score ranges from 0 to 8.

Expression of choice is tested by asking the patient to make a clear choice regarding the treatment. The score ranges from 0 to 2. Authorisation to use the scale was obtained from the authors and a printed copy of the permission letter has been attached in the appendix.

2. Brief Psychiatric Rating Scale

Developed by Overall and Gorhom in 1962, it is a popularly employed rating scale to assess the severity of psychiatric illnesses. It has been a validated and reliable tool in the assessment of psychosis.[123]

The scale consists of 18 items, namely, somatic concern, anxiety, emotional withdrawal, conceptual disorganization, guilt feelings, tension, mannerisms and posturing, grandiosity, depressive mood, hostility, suspiciousness, hallucinatory behaviour, motor retardation, uncooperativeness, unusual thought content, blunted affect, excitement and disorientation. Each of these are scored between 1-7, 1 being "absent", and 7 being "extremely severe" symptom. For items that are not assessed, a score of 0 is given.

Leucht et al (2008), concluded that a score of 31 on BPRS, corresponds to 'mildly ill', BPRS score of 41, corresponds to 'moderately ill' and a score of 53 corresponds to 'markedly ill'.[129]

3. Beck's Cognitive Insight Scale

It was developed by Aron T Beck in 2004. It is used to measure the level of insight in a patient. There are 2 sub-scales attached. Self-reflectiveness assesses the patients' willingness to observe the thoughts and consider alternate explanations for the same, and self-certainty scores, which assesses the confidence of the patient in his own beliefs. A composite score is obtained by subtracting the self-certainty score and the self-reflectiveness score.

Data Analysis

Data obtained was tabulated in Microsoft excel and subjected to appropriate statistical analyses. Descriptive statistics in the form of socio-demographic profile were presented as percentages for categorical variables, mean and standard deviation for continuous variables. The strength of association (p value) between the socio-demographic and clinical details for the group of patients with intact capacity to consent and impaired capacity to consent was calculated using unpaired t test and one-way ANOVA for continuous variables and Fisher's exact test and Chi-square test for categorical variables. p- value for comparison of the mean scores of various domains of MacCAT-T with clinical details, Comparing the mean BPRS scores and mean Beck's insight score for different domains of MacCAT-T was calculated using unpaired t test and one-way ANOVA. All tests were 2-tailed tests. Statistical significance was set at p value less than 0.05.

RESULTS

114 patients who met the inclusion criteria were approached for inclusion in the study. Out of the 114, 6 patients did not consent for participation, 4 were admitted in catatonic state and 4 patients came with extreme agitation, hence were not cooperative for examination and for participation in the study. Hence, 14 patients were excluded from the study making the final sample of 100 patients admitted with psychosis.

TABLE 1: SOCIO-DEMOGRAPHIC PROFILE OF THE STUDY SAMPLE

S.no	Variables	Subcategories	Observations n=100(%)
1.	Age (mean ± sd)		34.17 ± 10.69
2.	Sex		
		A) Male	55 (55%)
		B) Female	45 (45%)
3.	Marital status		
		Married	70 (70%)
		Unmarried	27 (27%)
		Separated	2 (2%)
		Widowed	1 (1%)
4.	Educational status		
		No formal education	10 (10%)
		Studied up to high school	48 (48%)
		High school	20 (20%)
		Graduate	22 (22%)

Table 1 shows the demographic profile of the patients included in the study. The mean age of the sample was 34.17 years with a standard deviation of 10.69 years. A slight male preponderance was seen (55% v/s 45%). 70 % patients were married. 10 % patients had no formal education while 20% and 22 % had studied till high school and graduation.

TABLE 2: CLINICAL PROFILE OF THE STUDY SAMPLE

S.no	Variables	Subcategories	Observations n=100(%)
1.	ICD-10 diagnosis		
		Paranoid schizophrenia (F 20)	45 (45%)
		Undifferentiated schizophrenia (F20.3)	22 (22%)
		Persistent delusional disorder (F 22.0)	4 (4%)
		ATPD without symptoms of schizophrenia (F 23.0)	12 (12%)
		ATPD with symptoms of schizophrenia (F 23.1)	3 (3%)
		Acute schizophrenia-like psychotic disorder (F 23.2)	1 (1%)
		Schizoaffective disorder, manic type (F 25.0)	4 (4%)
		Unspecified non-organic psychosis (F 29.0)	9 (9%)
2.	Duration of illness		
		<1 month	17 (17%)
		1 month-1 year	19 (19%)
		1 year-5 years	27 (27%)
		5 years- 10 years	20 (20%)
		>10 years	17 (17%)
3.	Number of previous admissions		
		0	47 (47 %)
		1	24 (24%)
		2	18 (18%)
		3	5 (5%)
		>3	6 (6%)
5.	BPRS score (mean ± sd)		41.4 ± 7.3
6.	Beck's insight score (mean ± sd)		-2.53 ± 3.73

FIGURE 2: DIAGNOSTIC SUBTYPES UNDER PSYCHOSIS AS PER ICD-10 DCR IN THE STUDY SAMPLE (corresponding to table 1)

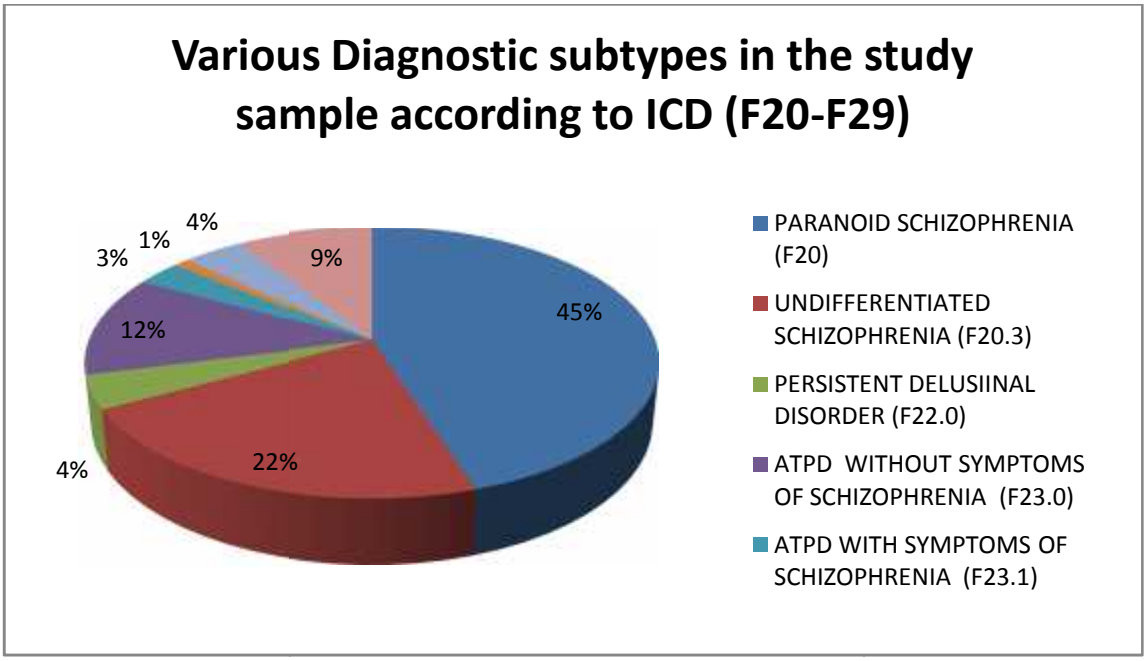


Table 2 depicts the clinical characteristics of the sample. As per the table and figure 2, 71% of the patients fell into the diagnosis of schizophrenia (ICD F20, 20.3) and schizoaffective disorder (ICD F25). 16 % were diagnosed as acute and transient psychotic disorders (ICD F23, 23.1, 23.2) and 13% fell into the diagnostic group of other psychotic disorders which included persistent delusional disorder and unspecified nonorganic psychosis (ICD F22, F29) (Figure 2).

Majority of the patients had a duration of illness of less than 1 year (36%), followed by a duration of illness less than 5 years (27%). Only 17% patients had a duration of illness more than 10 years.

47% had not been admitted for their illness before. The mean BPRS score was 41.4 ± 0.3, indicating moderate severity and mean Beck's insight score were -2.53 ± 3.73, which indicates a poor insight into their illness.

TABLE 3: PROPORTION OF PATIENTS' WITH INTACT CAPACITY TO CONSENT TO TREATMENT.

Status of capacity to consent	Observation n=100 (%)
Intact capacity to consent	23 (23 %)
Impaired capacity to consent	77 (77%)
Total	100 (100%)

Table 3 depicts the proportion of patients with presence of intact capacity to consent to treatment. It was found that 23 % patients had intact capacity to consent to treatment out of the entire study population.

TABLE 4: COMPARING THE PROPORTION OF PEOPLE DECLARED TO HAVE CAPACITY TO CONSENT WHEN TWO DIFFERENT CRITERIA ARE APPLIED

S.no	Criteria	Capacity n=100 (%)	Incapacity n=100 (%)	p value
1.	MHCA 2017	24	76	1.00
2.	Four legal criteria (MacCAT-T)	23	77	

FIGURE 3:COMPARISON BETWEEN PATIENTS WITH INTACT CAPACITY TO CONSENT TO TREATMENT AS PER MHCA 2017 CRITERIA AND FOUR LEGAL STANDARDS MENTIONED BY GRISSO AND APPELBAUM (MacCAT-T) (corresponding to table 4)

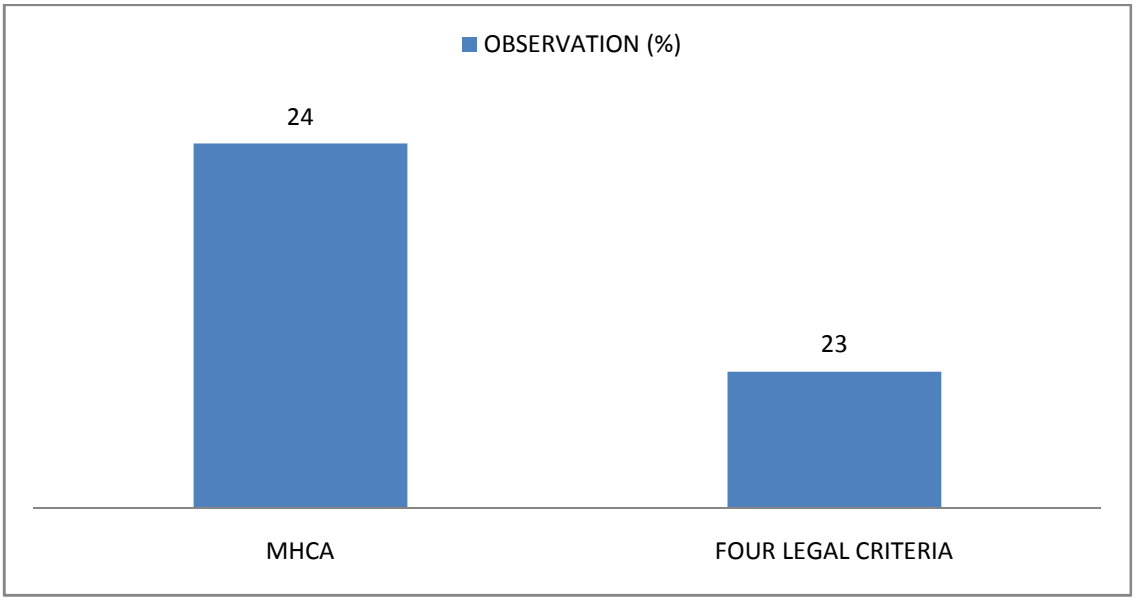


Table 4 and Figure 3 shown above, reveal the proportion of patients with capacity to consent and those with impaired decision making capacity, adjudged according to 2 criterions, which are as follows:- MHCA 2017 criteria, it takes into account 3 domains, understanding, reasoning and expression of a choice. The four legal criteria as mentioned by Grisso and Appelbaum, takes into consideration all the 4 domains as mentioned in MacCAT-T.

24 out of 100 were found to have intact capacity with the MHCA criterion and 23 out of 100 were found to have intact capacity as per the legal standards (MacCAT-T). There was no significant difference between the two criteria used for capacity assessment in this sample.

TABLE 5: DISTRIBUTION OF THE SAMPLE ACCORDNG TO VARIOUS SUBCATEGORIES OF THE 'UNDERSTANDING' DOMAIN OF CAPACITY ASSESSMENT AS PER MacCAT-T

S.no	Subcategory	scores	Observation (%) (n=100)
1.	Disorder	0-1	50 (50%)
		1.1-2	50 (50%)
	Mean and S.D		0.985 ± 0.467
2.	Treatment	0-1	50 (50%)
		1.1-2	50 (50%)
	Mean and S.D	1.3 ± 0.55	
3.	Risks and Benefits	0-1	56 (56 %)
		1.1-2	44 (44%)
	Mean and S.D		1.076 ± 0.55
4.	Total Understanding scores	0-3 (impaired understanding)	34 (34%)
		3.1-6 (intact understanding)	66 (66%)
	Mean and S.D		3.33 ± 1.31

Table 5 shows the mean scores for the 'understanding' domain of capacity assessment as per MacArthur Competency Assessment Tool For treatment (MacCAT-T). There are 3 sub-domains for understanding, understanding disorder (0-2), understanding treatment (0-2) and understanding the risks and benefits of the treatment (0-2). The total understanding score is a sum of the three subdomains and is rated from 0-6.If the total scores are above 50% cut-off value, understanding domain is considered to be intact. In our study, 66% individuals had scored above 3.1, hence had intact understanding. The mean score was 3.33 ± 1.31

TABLE 6: DISTRIBUTION OF THE SAMPLE ACCORDING TO VARIOUS SUBCATEGORIES OF THE 'APPRECIATION' DOMAIN OF CAPACITY ASSESSMENT AS PER MacCAT-T

S.no	Subcategory	scores	Observation (%) (n=100)
1.	Appreciating Disorder	0 (appreciation absent)	64 (64%)
		1 (partial acknowledgement)	15 (15%)
		2 (complete appreciation)	21 (21%)
2.	Appreciating Treatment	0 (appreciation absent)	45 (45%)
		1 (partial acknowledgment)	18 (18%)
		2 (complete appreciation)	37 (37%)
3.	Appreciation total scores	0 -2 (Impaired appreciation)	68 (68%)
	(0-4)	2.1-4 (Intact appreciation)	32 (32%)

Table 6 depict the mean scores for the 'appreciation; domain as per MacCAT-T. There are 2 sub-domains of this domain, appreciating disorder (0-2) and appreciating treatment (0-2). Total appreciation scores are a sum of the two sub-domains and are rated from 0-4. Appreciation is intact if the scores are above 50% of the total.

Majority of patients did not agree with the clinician's view of their illness and the need for treatment. Hence, 64% had absent appreciation of the illness and 45% had no appreciation of the treatment. Only 32 % individuals had scores 2.1 and above, hence had intact appreciation domain.

TABLE 7: DISTRIBUTION OF THE SAMPLE ACCORDING TO VARIOUS SUBCATEGORIES OF THE 'REASONING' DOMAIN OF CAPACITY ASSESSMENT AS PER MacCAT-T

S.no	Subcategory	scores	Observation (%) (n=100)
1.	Consequential reasoning	0	42 (42%)
		1	53 (53%)
		2	5 (5%)
	Mean and S.D		0.63 ± 0.57
2.	Comparative Thinking	0	65 (65%)
		1	28 (28%)
		2	7 (7%)
	Mean and S.D		0.42 ± 0.62
3.	Generating Consequences	0	61(61 %)
		1	35 (35%)
		2	4 (4%)
	Mean and S.D		0.43 ± 0.57
4.	Logical Reasoning	0	41 (41%)
		1	18 (18%)
		2	41(41%)
	Mean and S.D		1 ± 0.9
5.	Total Reasoning Scores	0-4 (impaired reasoning)	75 (75%)
		4.1-8 (intact reasoning)	25 (25%)
	Mean and S.D		2.49 ± 2.13

Table 7 depict the mean scores for the 'reasoning' domain as per MacCAT-T. It consists of 4 sub-domains, consequential reasoning (0-2), comparative thinking (0-2), generating consequences (0-2) and logical reasoning (0-2). Total reasoning scores are a sum of all four sub-domains and are rated from 0-8. Reasoning is intact if the scores are above 50% of the total. Twenty-five percent individuals had a score of more than 4.1, hence had intact reasoning domain.

TABLE 8: DISTRIBUTION OF THE STUDY SAMPLE ACCORDING TO VARIOUS SUBCATEGORIES OF THE 'EXPRESSING A CHOICE' DOMAIN OF CAPACITY ASSESSMENT AS PER MacCAT-T

S.no	Subcategory	Score	Observation n=100 (%)
1.	No choice/ no clear choice	0-1	16 (16%)
2.	States a clear choice	2	84 (84%)

Table 8 depicts the distribution of the sample according to the choices made in 'expression of choice' domain as per MacCAT-T. It is rated from 0-2. 0 for no choice made, 1 for not stating a clear choice, being ambivalent and 2 for a clear choice. Expression of choice is said to be intact if the patient is able to state a clear choice

In our study, 84% individuals were able to state a clear choice, hence had intact choice domain.

TABLE 9: DISTRIBUTION OF THE STUDY SAMPLE ACCORDING TO THE VARIOUS CHOICES MADE BY THE PATIENTS' ON ASSESSING THE 'EXPRESSION OF CHOICES' DOMAIN

S.no.	Choices	Observation n=100 (%)
1.	No choice made	16 (16%)
2.	No treatment	32 (32%)
3.	Oral antipsychotics	31 (31%)
4.	LAI	18 (18%)
5.	ECT	3 (3 %)

LAI: long acting injection, depot antipsychotic; ECT- electroconvulsive therapy

FIGURE 4:DISTRIBUTION OF THE VARIOUS CHOICES MADE BY THE PATIENTS' ON ASSESSING THE 'EXPRESSION OF CHOICES' DOMAIN(corresponding to table 9)

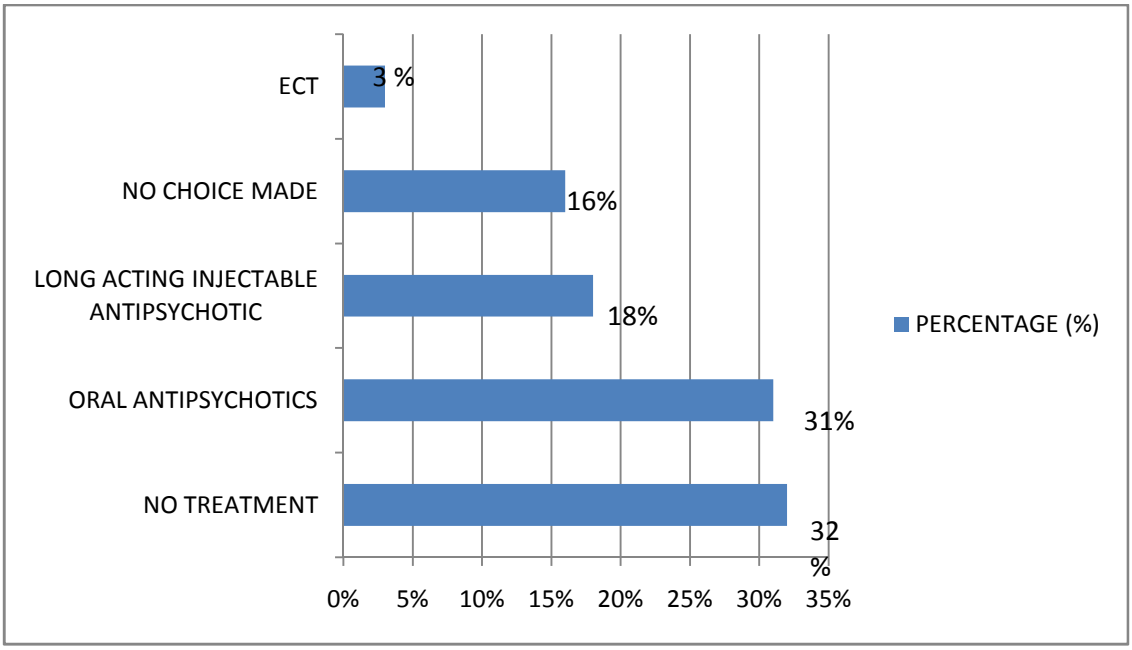


Table 9 and Figure 4 show the various choices made by the patients. A slightly more than half of the patients (52%) chose some form of treatment (31 % oral antipsychotics, 18% LAI, 3% ECTs). 31% refused any form of treatment and 16 % had no choice.

TABLE 10: COMPARISON OF THE SOCIO DEMOGRAPHIC CHARACTERISTICS OF PATIENTS, BETWEEN THOSE WITH INTACT CAPACITY AND THOSE WITH IMPAIRED CAPACITY TO CONSENT

S.No	Variables	Subcategories	Intact capacity n=24 (%)	Impaired Capacity n=76 (%)	P value
1.	Age (mean± SD)		31.65±10.23	34.68±10.96	0.2331
2.	Sex				
		Male	13 (54.17%)	42 (55.26%)	1.00
		Female	11 (45.83%)	34 (44.74%)	
4.	Educational status				
		No formal education	10 (10%)	10 (13.16%)	0.228
		Studied up to high school	13 (54.17%)	35 (46.05%)	
		High school	4 (16.67%)	16 (21.05%)	
		Graduation	7 (29.17%)	15 (19.74%)	

Table 10 shows the comparison between the demographic details of patients who had capacity to consent to treatment and those with incapacity as per MacCAT-T. There was no significant difference between the two groups with regards to age and gender distribution.

There was a higher proportion of individuals studied till high school and graduation in the group with intact capacity to consent (45.84 vs 40.79). The difference was not found to be significant between the two groups,

TABLE 11: COMPARISON OF THE CLINICAL CHARACTERISTICS OF PATIENTS, BETWEEN THOSE WITH INTACT CAPACITY AND THOSE WITH IMPAIRED CAPACITY TO CONSENT, AS PER MHCA 2017 CRITERIA

S.no	Variables	Subcategories	Intact capacity	Impaired capacity	P value
1.	Duration of illness				
		> 1 month	5 (20.83%)	12 (15.79%)	
		1 month- 1 year	3 (12.50%)	16 (21.05%)	
		1 year- 5 years	9 (37.50%)	18 (23.68%)	
		5 years- 10 years	1 (4.17%)	19 (25.0%)	0.997
		> 10 years	3 (25%)	11 (14.47%)	
2.	No. Of previous admissions				
		0	14 (58.3%)	33 (43.42%)	
		1	3 (12.50%)	21 (27.63%)	
		2	5 (20.83%)	13 (17.11%)	0.563
		3	1 (4.17%	4 (5.26%)	
		>3	4.17%	5 (6.58%)	
3.	ICD-10 Diagnosis				
		Paranoid schizophrenia (f20.0)	11 (45.83%)	34 (44.74%)	
		Undifferentiated schizophrenia (f20.3)	3 (12.50%)	19 (25.0%)	
		PDD (f22.0)	2 (8.33%)	2 (2.63%)	
		ATPD, without symptoms of schizophrenia (f23.0)	3 (12.50%)	9 (11.84%)	0.8158
		ATPD, with symptoms of schizophrenia (f23.1)	1 (4.17%)	2 (2.63%)	
		Acute schizophrenia	0	1 (1.32%)	

		like disorder (f23.2)			
		Schizoaffective disorder, manic type (f25.0)	1 (4.17%)	3 (3.95%)	
		Unspecified non organic psychosis (f29.0)	3 (12.50%)	6 (7.89%)	
4.	BPRS Score		37.75±5.01	43.86±7.29	**0.0002*** **(unpaired t test)**
5.	Beck's insight score		-0.125±3.65	-3.29±3.42	**0.0002*** **(unpaired t test)**

*significant, $p<0.05$;

PDD: Persistent Delusional Disorder; ATPD: Acute And Transient Psychotic Disorder; LAI: Long Acting Injection, Depot Antipsychotic; ECT- Electroconvulsive Therapy

FIGURE 5: COMPARISON OF THE MEAN BPRS SCORE BETWEEN PATIENTS WITH INTACT CAPCITY AND THOSE WITH IMPAIRED CAPACITY TO CONSENT (corresponding to table 11)

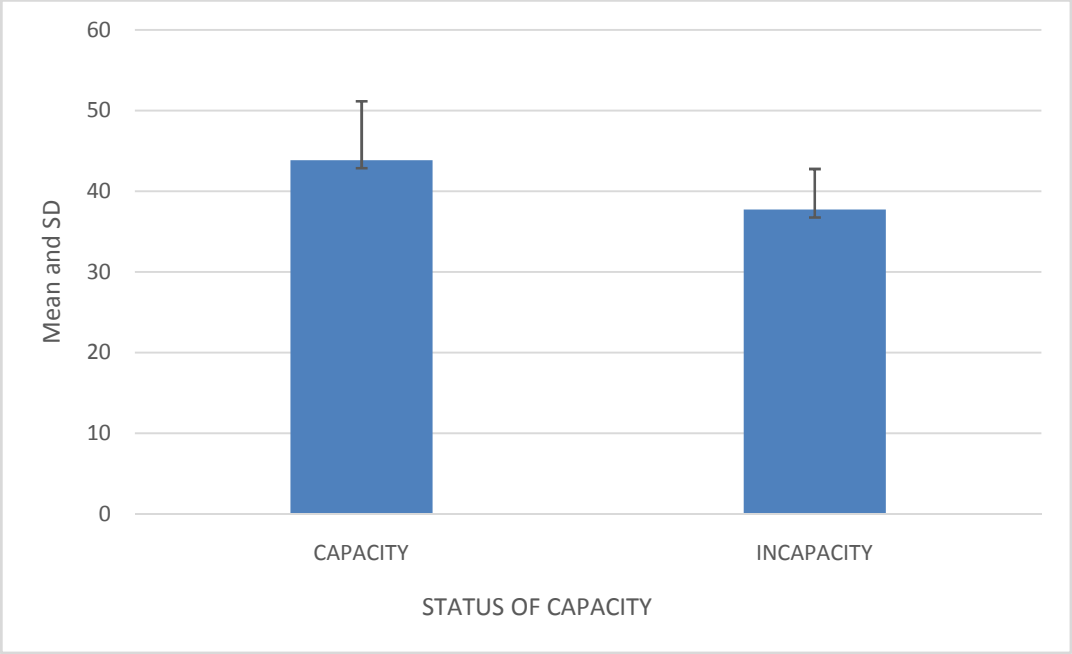


FIGURE 6: COMPARISON OF THE MEAN BECK'S INSIGHT SCORE BETWEEN PATIENTS WITH INTACT CAPCITY AND THOSE WITH IMPAIRED CAPACITY TO CONSENT (corresponding to table 11)

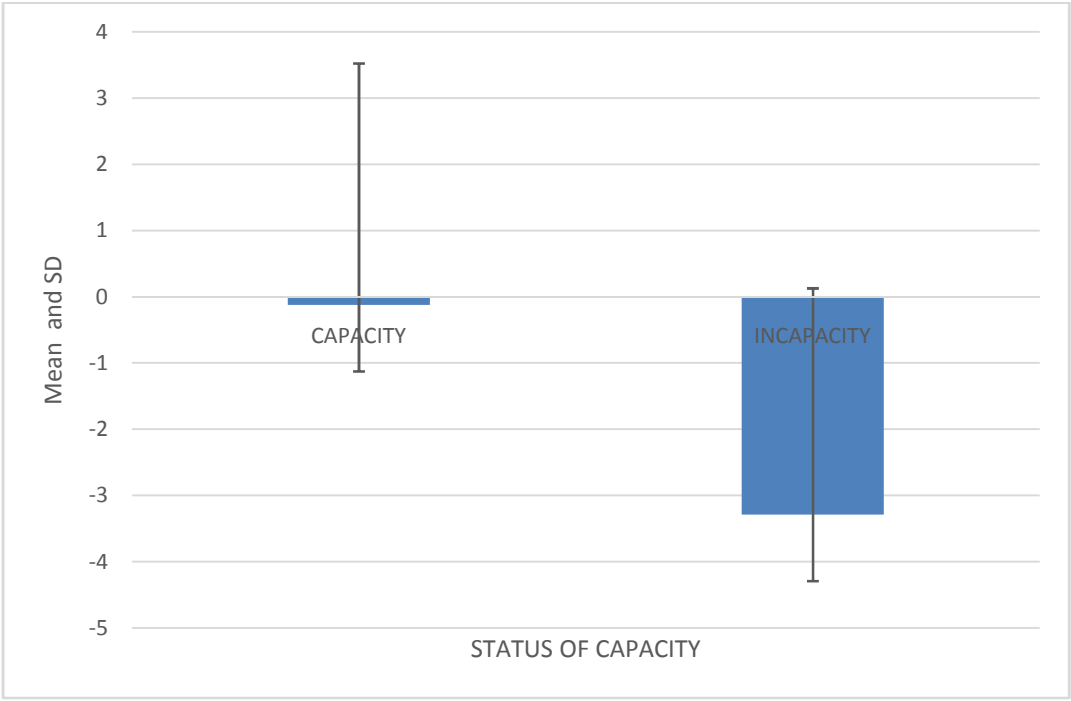


Table 11 shows the comparison of the clinical details between capacity and incapacity group. Capacity group had more individuals who had their duration of illness between 1 to 5 years (37.5 %), while incapacity group had more individuals with duration of illness between 5 to 10 years (25%). Capacity group had 62.5 % patients with a diagnosis of schizophrenia and schizoaffective disorder and 73.69 % patients from the incapacity group fell into the same diagnostic group. However, there was no statistically significant difference noted between the two groups.

Table 11 and figure 5 show the difference of mean BPRS scores between capacity and incapacity group. It was found that higher severity of illness was associated with poorer performance on MacCAT-T The difference between the mean BPRS score for intact capacity group and impaired capacity group was found to be statistically significant (37.75 ± 5.01 vs 43.86 ± 7.29) (p=0.0002).

Table 11 and figure 6 show the difference between the mean Beck's Insight score between the two groups. It was found that poorer insight into the illness was associated with poorer performance on MacCAT-T The difference between the mean Beck's insight score for intact capacity group and impaired capacity group was found to be statistically significant (-0.125±3.65 vs-3.29± 3.42) (p = 0.0002).

TABLE 12:ASSOCIATION OF THE MEAN UNDERSTANDING SCORES BETWEEN THE TOTAL POPULATION AND THE SUBCATEGORIES OF THE CLINICAL CHARACTERISTICS AS ASSESSED BY MacCAT-T

S. No	Variables	Subcategory	Mean Understanding Score	N=100	p VALUES
1.	Total Population		3.33 ± 1.31	100	
2.	Duration of Illness				
		< 1 month	2.88 ± 1.43	17	**0.0003 *(one-way ANOVA)**
		1 month- 1 year	3.56 ± 1.24	19	
		1 year- 5 years	3.24 ± 1.14	27	
		5 years – 10 years	4.7 ± 0.98	20	
		>10 years	3.30 ± 1.38	17	
3.	Previous Admissions				
		0	3.37 ± 1.40	47	**0.0036 *(one-way ANOVA)**
		1	3.2 ± 1.03	24	
		2	4.4 ± 1.43	18	
		3	4.4 ± 0.181	5	
		>3	2.40 ± 1.00	6	
4.	Diagnosis				
		Schizophrenia and Schizoaffective Disorder	3.50 ± 1.29	71	0.2796
		Acute Psychosis	2.81 ± 1.45	16	
		Other Psychotic Disorders	3.25 ± 0.81	13	

*significant, $p<0.05$

LAI: LONG ACTING INJECTABLE, DEPOT ANTIPSYCHOTIC; ECT-ELECTROCONVULSIVE THERAPY

FIGURE 7: COMPARISON OF MEAN OF THE TOTAL UNDERSTANDING SCORES WITH THE MEAN UNDERSTANDING SCORES ACCORDING TO THE TOTAL DURATION OF ILLNESS OF THE PATIENTS. (Corresponding to table 12)

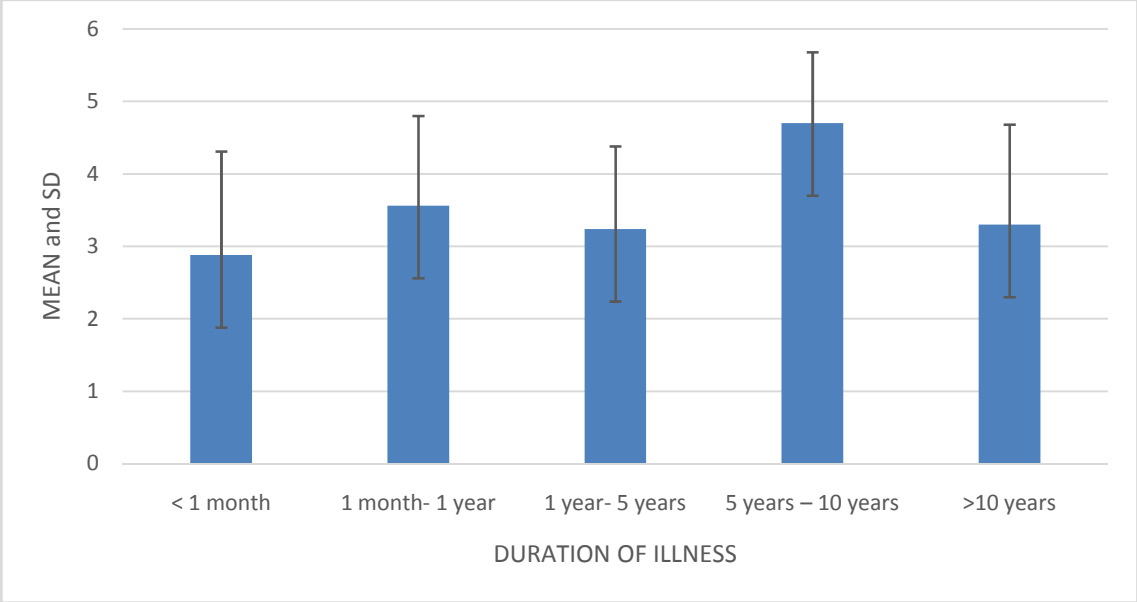


FIGURE 8: COMPARISON OF MEAN OF THE TOTAL UNDERSTANDING SCORES WITH THE MEAN UNDERSTANDING SCORES ACCORDING TO THE NUMBER OF TIMES A PATIENT HAS BEEN PREVIOUSLY ADMITTED. (Corresponding to table 12)

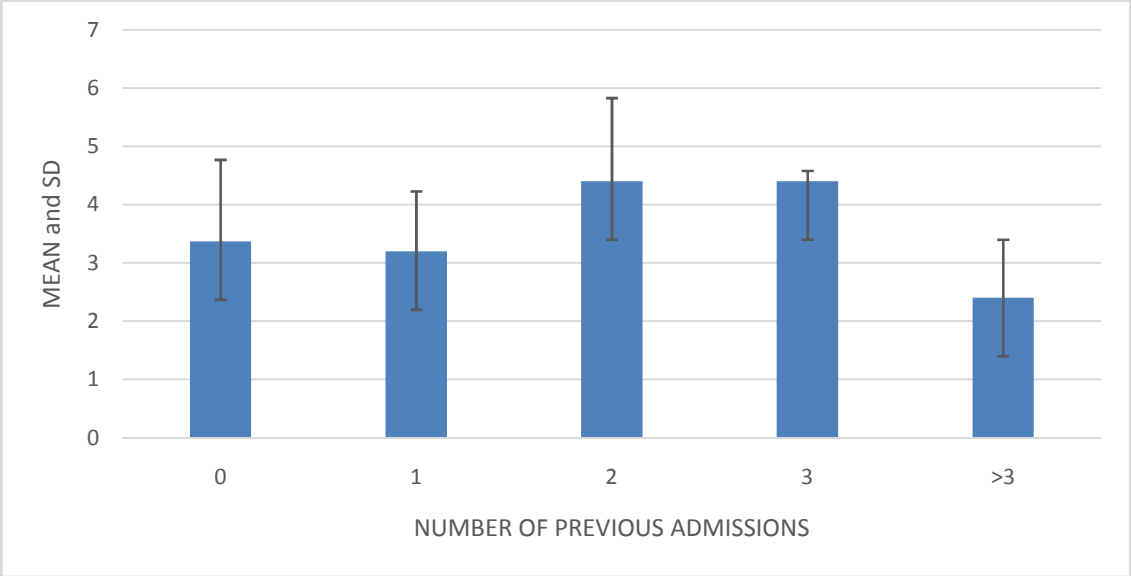


Table 12 shows the association of mean understanding scores for the total population and the clinical details of the patients. It was found that as the duration of illness increased, the understanding scores also improved. This trend was noted till duration of illness being 5-10 years of illness and a slight reduction in scores was noted beyond 10 years of illness (p value= 0.0003) (figure 7). Patients with history of previous admissions for their illness had better scores till 3 admission. Patients with more than 3 admissions showed poorer understanding than the total mean scores (p value= 0.0036) (figure 8).

The test for significance was also applied for the comparison of other domains of capacity and demographic and clinical variables of the patient. No statistically significant difference was obtained.

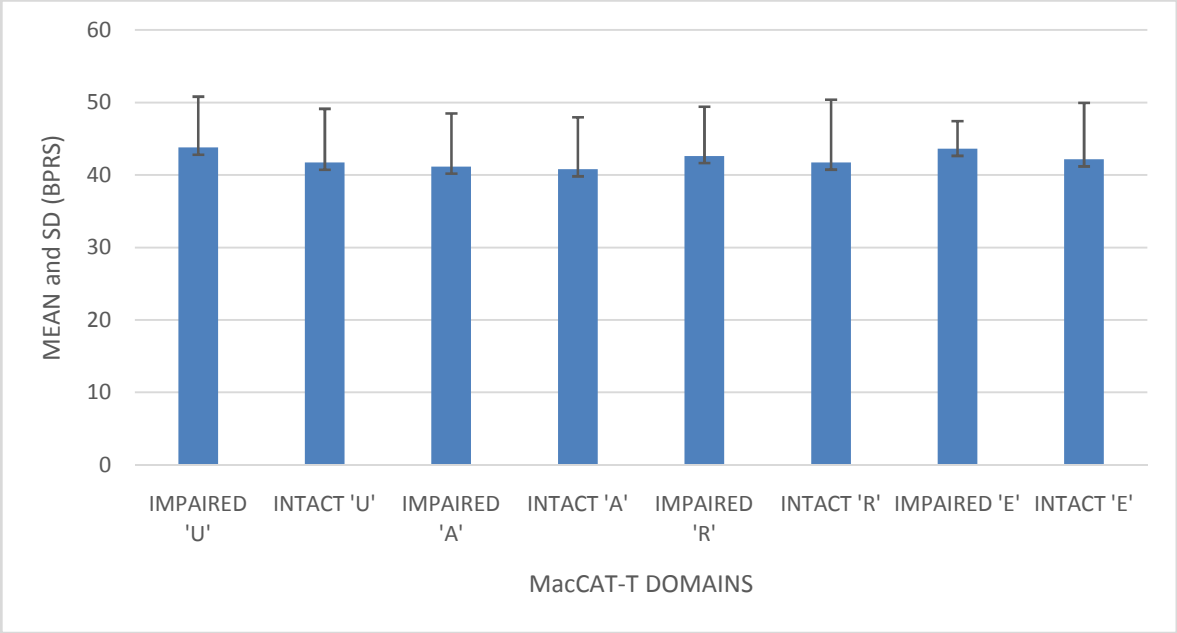
TABLE 13: COMPARISON OF SEVERITY OF ILLNESS BETWEEN PATIENTS WITH INTACT DOMAINS AND IMPAIRED DOMAINS ACCORDING TO MacCAT-T.

S.No	Domains of MacCAT-T	Sub-categories	BPRS Score (Mean±SD)	n=100	p value
1.	Understanding				
		<3 (impaired understanding)	43.79 ± 7.00	34	0.3441
		>3 (intact understanding)	41.70 ± 7.41	65	
2.	Appreciation				
		<2 (impaired appreciation)	43.16 ± 7.31	70	**<0.0001* (unpaired t test)**
		>2 (intact appreciation)	40.80 ± 7.14	30	
3.	Reasoning				
		<4 (impaired reasoning)	42.62 ± 6.78	76	0.598
		>4 (intact reasoning)	41.72 ± 8.66	24	
4.	Expression of choice				
		0-1 (impaired expression domain)	43.62 ± 3.78	**16**	**<0.0001* (unpaired t test)**
		2(intact expression domain)	42.16 ± 7.78	84	

*significant, p<0.05

BPRS- Brief Psychiatric Rating Scale

FIGURE 9: COMPARISON OF MEAN BPRS SCORES BETWEEN PATIENTS WITH INTACT DOMAINS AND IMPAIRED DOMAINS ACCORDING TO MacCAT-T.



'u'- understanding; 'A'- appreciation; 'R'- reasoning; 'E'-expression of choice

Table 13, figure 9 depicts the comparison of severity of illness in individuals who had intact domains (understanding, appreciation, reasoning, expression of choice) and impaired domains in MacCAT-T. There was no significant difference between BPRS scores for people with intact and with impaired understanding and with respect to reasoning scores. Understanding and reasoning were better in patients with intact capacity however, the difference was not significant.

There was a significant difference ($p<0.0001$) in the appreciation and expression of choice domain of patients with and without capacity to consent. Patients with intact appreciation and those who were able to express a choice had lesser BPRS scores as compared to patients with impaired domain.

TABLE 14: COMPARISON OF LEVEL OF INSIGHT BETWEEN PATIENTS WITH INTACT DOMAINS AND IMPAIRED DOMAINS ACCORDING TO MacCAT-T

S.No	Domains of MacCAT-T	Sub-categories	Beck's Insight Score (Mean±SD)	n=100	p value
1.	Understanding				
		<3 (impaired understanding)	-3.23 ± 3.54	34	0.1708
		>3 (intact understanding)	-2.15 ± 3.799	65	
2.	Appreciation				
		<2 (impaired appreciation)	-2.67 ± 3.52	70	0.5565
		>2 (intact appreciation)	-2.19 ± 4.18	30	
3.	Reasoning				
		<4 (impaired reasoning)	-2.57 ± 3.50	76	0.8454
		>4 (intact reasoning)	-2.4 ± 4.34	24	
4.	Expression of choice				
		0-1 (impaired expression domain)	-3.31 ± 3.51	16	0.3617
		2(intact expression domain)	-2.38 ± 3.75	84	

Table 14 depicts the comparison of the level of insight between the patients who had intact domains of capacity and those who had impaired domains of capacity as per MacCAT-T. The difference between the scores on the insight scale were not found to be significant in any of the domains. It was noted that patients with better insight scores belonged to the category of intact understanding, appreciation, reasoning, and expression of choice.

DISCUSSION

With the recent change in the mental health legislations and introduction of the MHCA 2017, it has become mandatory to assess the capacity to consent to treatment. It becomes even more important to assess the capacity to consent when the admitting a patient to the psychiatry in patient unit is considered. If the patient has the capacity to consent patient must be admitted as per the protocol for independent admission as per MHCA 2017. If the patient doesn't possess the capacity to consent and required in-patient care as per the assessment of the psychiatrist, the patient must be admitted as per the protocol for high support admission and the capacity should be re-assessed every week.

If the mental health practitioner fails to do so, they will be found in violation of the rights of the patient.

Our study assessed the capacity to consent to treatment in patients with functional psychosis and found that the mean age of the sample was 34.17 years. Majority of the study population had moderate severity of illness with poor insight. Our study revealed that around one- fourth of the patients admitted with a diagnosis of psychosis had intact capacity to consent to treatment as they had intactness in all four domains of MacCAT-T.

According to MacCAT-T, majority of the patients had intact understanding and expression of choice domains. Majority patients had impaired appreciation and reasoning domains. Our study also revealed that patients with impaired capacity to consent to treatment had higher severity of psychosis and poorer level of insight as compared to patients with intact capacity to consent to treatment.

Higher severity of illness was also associated with impaired appreciation and expression of choice domains of capacity to consent to treatment.

1. PREVALENCE OF CAPACITY AND INCAPACITY IN THIS STUDY

To assess the capacity of the patient, the MacCAT-T was used. It is a semi-structured tool which doesn't have a threshold score to determine the presence or absence of capacity to take treatment decisions. However, the scores which are 50 % and below for the four abilities mentioned in the tool, indicate severely affected abilities in those domains and are more likely to demonstrate incapacity to consent to treatment.[139]

In this study, patients with impairments in any one of the three subscales of MacCAT-T, which are needed for intact capacity as per MHCA 2017 (understanding, appreciation, and communicating a choice) were regarded to not have capacity to take treatment decisions. 23% of the patients were found to have capacity and 77 % did not possess the capacity to consent to treatment(table 3). Studies done by Grossman et al (1980), Hoffman and Srinivasan et al(1992), showed that around 25-50 % patients with acute psychosis and schizophrenia had no decision making capacity.[78,140]Fernandez et al (2017) studied the relationship between changes in capacity to consent, symptoms and functioning. The study revealed that 62.5 % had capacity based on the initial assessment.[139] In another study conducted by Cairns et al (2005), to find out the prevalence and predictors of mental incapacity in psychiatric in-patients, they found that 52.6% of the participants, had capacity.[6]Mandarelli et al (2018), in his study to evaluate the decision making capacity in involuntarily admitted psychiatric patients, found a prevalence of 22% capacity.[88] Capdevielle et al (2009), found that 55-61% patients had low or partial insight.[4]

Our study revealed lesser proportion (23 %) of people having intact capacity to consent to treatment as compared to the findings of other studies where more patients had intact capacity to consent to treatment (40-60%). This difference can be attributed to the patients being assessed in the acute phase of the illness (within 24 hours) and were not on any treatment.

2. DIFFERENCE IN THE PREVALENCE OF CAPACITY AS PER MHCA 2017 AND FOUR LEGAL CRITERIA OF GRISSO AND APPELBAUM.

The standards to determine capacity vary amongst various jurisdictions. Grisso and Appelbaum (1998) suggested that the legal standards to determine the same are among one of the four mentioned criterion (understanding relevant information, appreciating the disorder and need for treatment, reasoning and weighing the information rationally).[93]

In the current study, 24% patients had capacity when judged by MHCA criteria and 23 % patients had capacity according to the four legal standards. This difference was not found to be significant. There are no studies which have tried to show the difference between the two methods (table 4, figure 3).

As the criteria to assess capacity becomes more stringent, it would require more rules to be satisfied to adjudge the capacity to consent to be intact and thus prevalence of incapacity would be greater, as. Any capacity assessment should, have the balance approach, wherein, the balance should be between protecting the rights of the patient and safeguarding the patient and others from harm.

3. PERFORMANCE OF THE SAMPLE ON VARIOUS DOMAINS OF MacCAT-T

a. UNDERSTANDING

This domain is assessed under 3 sub domains: - understanding disorder, understanding treatment, and understanding risks and benefits. They are scored from 0 to 2 individually, which makes the total understanding score to be 6. For the understanding domain to be intact, it should be more than 50 % of the total score.

0.467. This reflects a poor understanding of the disorder amongst the study population. The mean score for understanding treatment and risks and benefits and treatment was 1.3 ± 0.5 and 1.076 ± 1.31 respectively. This score was above average and hence reflects good understanding of the treatment details and the risks and benefits associated with the treatment. Hence the total mean understanding score was 3.33 ± 1.31, which was more than half of the maximum score. It means that there is a good understanding of the disorder amongst the population of the study (table 5). In a study by Grisso et al (1995), to compare the standards for assessing the decision making capacity of the patients, 72 % patients with schizophrenia had good understanding scores.[138] Mandarelli et al (2017) in their study also had above average mean total understanding scores of 4.0±1.5 for schizophrenic spectrum disorders.[88] In his study, Fernandez et al (2017), observed that at the time of admission, understanding scores for capacity group was 4.2 and 1.4 for the incapacity group. These scores did improve upon treatment.[137]Capdevielle et al (2009), in their study had mean scores of 4.55± 1.56 for understanding.[141]Owen et al(2013) found that psychiatric patients despite good understanding, had incapacity. This was attributed to deficits in appreciation despite having good reasoning.[142]

b. APPRECIATION

Appreciation is assessed for the disorder and for the treatment. This domain is also scored from 0-2 and has a total score of 4. It should be more than 50% of the total score to be intact.

Sixty-four patients (64%) in this study did not appreciate the disorder and could not relate to the disorder and the symptoms explained. Forty- five patients (45%) had poor appreciation of the treatment and did not think that they would be helped by the treatment. The mean appreciation score for the population was 1.48±1.57 and a combined proportion of 68% patients had below average score on appreciation, hence majority had impairment on this domain (table 6). Fernandez et al (2017) observed that baseline appreciation scores for patients with intact capacity was 1.4.[137] Bilanikis et al (2017), in their study, to explore the decision making capacity in patient with schizophrenia, had appreciation scores to be 2.14 ± 1.31.[143]Mean appreciation scores as observed by Mandarelli et al (2017), in his study, were 1.6±1.4.[88] These findings do suggest that appreciation is poor in most patients with psychosis. For patients with psychiatric diagnoses, having adequate understanding, appreciation has shown to have good sensitivity and specificity in determining capacity. Even in patients with good understanding but impaired capacity, they had deficits in appreciation despite good reasoning.[142]

c. REASONING

Reasoning domain is assessed under the headings of consequential reasoning, comparative reasoning, generating consequences and logical reasoning. Each domain

is scored between 0-2. The total score for the reasoning domain is 8, a score of more than half indicates intact reasoning domain.

The study sample had a mean consequential reasoning score of 0.63 ± 0.57, a mean comparative reasoning score of 0.42 ± 0.62, mean comparative reasoning score of 0.43 ± 0.57, logical reasoning score of 1 ± 0.9. The total reasoning score was 2.49 ± 2.13 (Table 7), which was below the average score and hence majority of the patients in our study had an impaired reasoning domain. Owen et al (2013) found that 100% of psychiatric patients taken up in his study had poor reasoning[142]. Fernandez et al (2017) found that patients with incapacity had a baseline mean reasoning score of 0.3, those with capacity had a mean score of 3.9. Bilanikis et al (2017), reported mean scores of 3.71±2.39. Mandarelli et al (2017), in their study, reported mean scores of 3.5 ± 2.7 in the population of schizophrenia spectrum disorders. In his study, Grisso et al (1995) found that 24 % patients with schizophrenia had impaired reasoning scores. These finding suggest that patients with psychosis have an impaired reasoning domain. Vollmann et al(2003),in his study regarding competence of mentally ill patients, pointed out that patients with schizophrenia had clear deficits in reasoning,[144] Reasoning, taken alone, is a poor test with low sensitivity for assessing decision making capacity in a psychiatric patient population.[142]

d. EXPRESSION OF CHOICE

This criterion is assessed based on, if the patient can express a clear choice regarding the treatment modality preferred, including no treatment. It is scored from 0 to 2. 0 is scored when the patient does not express a clear decision, 1 is scored when patient is ambivalent between 2-3 choices and a score of 2 is given when the patient is able to give a clear-cut choice.

In this study, 84% patients were able to state a clear choice. The mean expression of choice score for the study was 1.67 ± 0.736. Amongst the choices made, 32% opted to receive no treatment, 31% opted for oral antipsychotics, 18 % opted for long-acting antipsychotics, 3% opted for electro-convulsive therapy and 16% did not state any choice. In our study majority of the patients, had intact expression of choice (Table 8). According to the results of Capdevielle et al (2009), the mean expression of choice for patients was 1.45 ± 0.67. Bilanakis et al (2017), had mean results of 1.61 ± 0.66. If there is an obvious loss of expression of choice such as, patients in stupor, extreme agitation or obvious ambivalency, this domain is considered to be impaired and by extension capacity is assumed to be impaired. In a study done by Vollmann et al (2003), 93% patients received a score of 2 on this domain.[144]

4. COMPARISON OF THE SOCIO-DEMOGRAPHIC CHARACTERISTICS OF THE PATIENTS WITH CAPACITY AND THOSE WHO HAD INCAPACITY TO MAKE TREATMENT DECISIONS

In our study, the patients belonging to intact capacity to consent group were relatively younger as compared to those belonging to impaired to capacity to consent (31.65 yrs Vs 34.68 yrs). There was a higher proportion of males in both the groups. There were a higher proportion of patients studied till high school and graduates in the intact capacity to consent group. However, these differences were not statistically significant. (Table 10). These findings were consistent with those in the studies done by Vollmann et al (2003),who in his study found no statistically significant difference between patients of capacity and incapacity group with regards to age, sex, education status of the patient.[144] Owen et al (2013),(2008) and Raymont et al(2004), also found that age and gender had no association with capacity to consent.[89,142,145]

However, one study showed differently. Curley et al (2019), in his study to find a linear relationship of capacity between voluntary and involuntary admitted patients and find an association between age and mental capacity. He found that decision making capacity is inversely correlated with age. There was a significant association with employment status.They also attributed the presence of incapacity and unemployment to the educational status of the individuals.[146]

5. COMPARISON OF THE CLINICAL CHARACTERISTICS OF THE PATIENTS WITH CAPACITY AND THOSE WITH INCAPACITY TO MAKE TREATMENT DECISIONS.

Factors such as diagnosis, duration of illness were compared in both the groups, however the difference was not statistically significant.

The severity of illness was found to be more (higher mean BPRS scores) in impaired capacity to consent group as compared to intact capacity to consent group and the difference was found to be statistically significant (43.86±7.29 vs 37.75±5.01) (p value =**0.0002)** (table 11, Figure 5).

These findings were similar to the results obtained by Owen et al (2008), who in their study to perform a detailed descriptive analysis of clinical associations of decisional capacity. They found that high total BPRS scores and unusual thought content were associated with impaired capacity to consent to treatment (Hedges g = 1.07 (0.58 to 1.56))[147]

These findings were different from those in other studies. In his study Bilanakis et al (2017), found no significant correlations with the MacCAT-T scores.[87] The mean BPRS scores for a population of 9% psychiatric population, in a study done

by Cairns et al (2004), was 32.3 ± 6.2.[6] Also, in studies done by Jacobs et al(2008) and Kovnick et al (2003), they found no significant correlation between the psychoticism cluster of BPRS (hallucinations, unusual thought content and conceptual disorganisation) and incapacity.[128,135]

It was also found that poor insight was also significantly associated with impaired capacity to consent. Patients with impaired capacity to consent had more negative scores on Beck's cognitive insight scale as compared to those with intact capacity to consent. (-3.29 ± 3.42 vs – 0.125 ± 3.65) (p value= **0.0002**)

The above findings were similar to those in a study by Owen et al (2008) in which they aimed to test associations between decisional capacity, psychopathological variables, particularly insight. They found that low insight scores were associated with impaired capacity to consent. The poor insight was more in association with incapacity in psychotic and bipolar disorder (Hedges g= -1.99 (-1.43 to -2.54).[147]

Capdeviellie et al (2009), in their study was to evaluate the association between capacity to consent and insight in patients suffering from schizophrenia found that appreciation and reasoning measures of MacCAT-T were negatively correlated all the dimensions of the Scale to Assess Unawareness of Mental Disorder (SUMD) scale (Mental disorder, medication, consequences, awareness and attribution). Poor insight level was linked with lower appreciation of benefits and risks and lower reasoning scores (comparative reasoning)[141]

However, these findings were different from those in a study done by Jeste et al(2006), who in their study found no association between capacity to consent and level of insight.[134]

6. ASSOCIATION OF SEVERITY OF PSYCHOSIS (BPRS SCORES) WITH DIFFERENT DOMAINS OF CAPACITY.

It was found that the mean BPRS scores for the groups having intact understanding, appreciation, reasoning, and expression of choice domains were higher than those with impairments in said domains (i.e. 50% or less scores). The difference was significant only for appreciation (43.16 Vs 40.80) and expression of choice (43.62 Vs 42.16) domains, with a significant p value of **<0.0001.** Thus, higher the severity of the illness, the poorer is the appreciation of the illness and treatment, and poorer is the ability to take a decision and express the same.

As mentioned earlier, in patients with psychiatric illness, appreciation has better sensitivity to detect impairments in capacity.[142]

Majority of the findings of our study were similar to the results published previously such as the association of the severity of psychosis and poor level of insight with the impaired capacity to consent to treatment and patients with psychosis having impaired appreciation and reasoning domains.

Some results were not congruent with those mentioned previously such as the prevalence of impaired capacity to consent to treatment. Higher proportion of patients had impaired capacity to consent to treatment (77%). This difference could be attributed to the patients were taken up for the study in their acute phase of the illness and not being on treatment.

STRENGTHS OF THE STUDY

1. Introduction of the concept of capacity in Mental Healthcare Bill 2017, is a recent advancement. It has made the assessment of capacity to consent to treatment for all PMI to take decisions regarding treatment mandatory. There are no studies done on this topic by far. This is the first study to be undertaken regarding capacity assessment to consent to treatment in India.
2. The tools used in the study (MacCAT-T, BPRS, Beck's Cognitive Insight scale) are used globally and are standardised with high inter-rater reliability and validity.
3. Apart from assessing the prevalence of capacity in the study population (primary aim), an effort to find the probably factors affecting the same has also been made.

LIMITATIONS OF THE STUDY

1. The sample size could have been greater to have a greater insight into the prevalence of capacity amongst patients with psychosis
2. This study only included patients with a diagnosis of psychosis. To assess the capacity to consent to treatment amongst other diagnostic subtypes like Obsessive- compulsive disorder, substance use disorder could throw more light onto the topic of capacity in psychiatric patients.
3. MacCAT-T is a semi-structured tool. It guides towards assessment of capacity and the impairments in various domains of capacity; however, it does not give a dichotomous result of presence or absence of incapacity.
4. It is presumed that most of the patients in maintenance and remission phase would have good capacity to consent to treatment. The assessment of capacity was not

done for patients in maintenance or remission phases of the illness and only acutely ill patients were taken up for the study.

5. Assessment of the capacity to consent was carried out within 24 hrs of admission of the patient. Serial assessments might give a better idea regarding capacity to consent and the recovery factors.

CONCLUSION

The study showed that not all the patients diagnosed with psychosis are incompetent to consent to treatment. According to the current study, approximately one-fourth of the patients had intact capacity to consent to treatment.

Out of the four domains for assessment of capacity, patients with impaired appreciation and expression of choice domain had more BPRS scores. Thus, more the severity of the illness, poorer was the acceptance of the illness, the need for treatment (appreciation) and the ability to express a choice (Expression of choice).

The socio-demographic profile of the patient did not have a significant association with the abilities related to capacity assessment. It was noted that severity of illness along with greater impairment of insight might be few of the contributing factors towards incapacity.

SUMMARY

India has seen a recent change in the legislations governing mental health. MHCA 2017 was introduced in 2018 and is a betterment over the previous MHA 1987, it is more patient centric and provides more autonomy to the patient and ensures that their rights should be respected. It has also made the assessment of capacity to consent to treatment mandatory to ensure maximum autonomy. The present study was taken up with the aim to assess the capacity to consent to treatment in patients with functional psychosis.

The present study was a one-year descriptive cross-sectional study which was conducted in the Department of Psychiatry, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi from 1st January 2019 to 31st December 2019. A total of 100 patients with a diagnosis of psychotic disorders according to ICD-10 DCR, who were admitted in the psychiatric ward were taken up for the study after due consent. Patients in catatonia or excessive agitation were not taken up for the study. Patients were interviewed regarding capacity assessment within 1-2 days of admission using MacCarthur Competency Assessment Tool for treatment. (MacCAT-T). Patients were also assessed for severity of the psychotic symptoms using Brief psychiatric rating scale (BPRS). Appropriate statistical tests were applied.

Patients were scored on the sub-scales of MacCAT-T, namely: - understanding, appreciation, reasoning, and expression of choice. Impairments in the respective domains were considered if the patient scored 50% or less. They were adjudged to have capacity according to the intactness of the domains provided by MHCA 2017. Unpaired t test and One- way ANOVA were used to compare the results of MacCAT-T scores, BPRS and Beck's insight score between the capacity and incapacity group.

23 % patients with psychosis were found to have intact capacity. Educational level was better in patients with capacity. They also had relatively lesser scores on BPRS and Beck's insight score.

Thus, it is imperative to examine the capacity of the patient before deeming the patient to have incapacity, thereby, protecting the rights of the patient and protection from harm.

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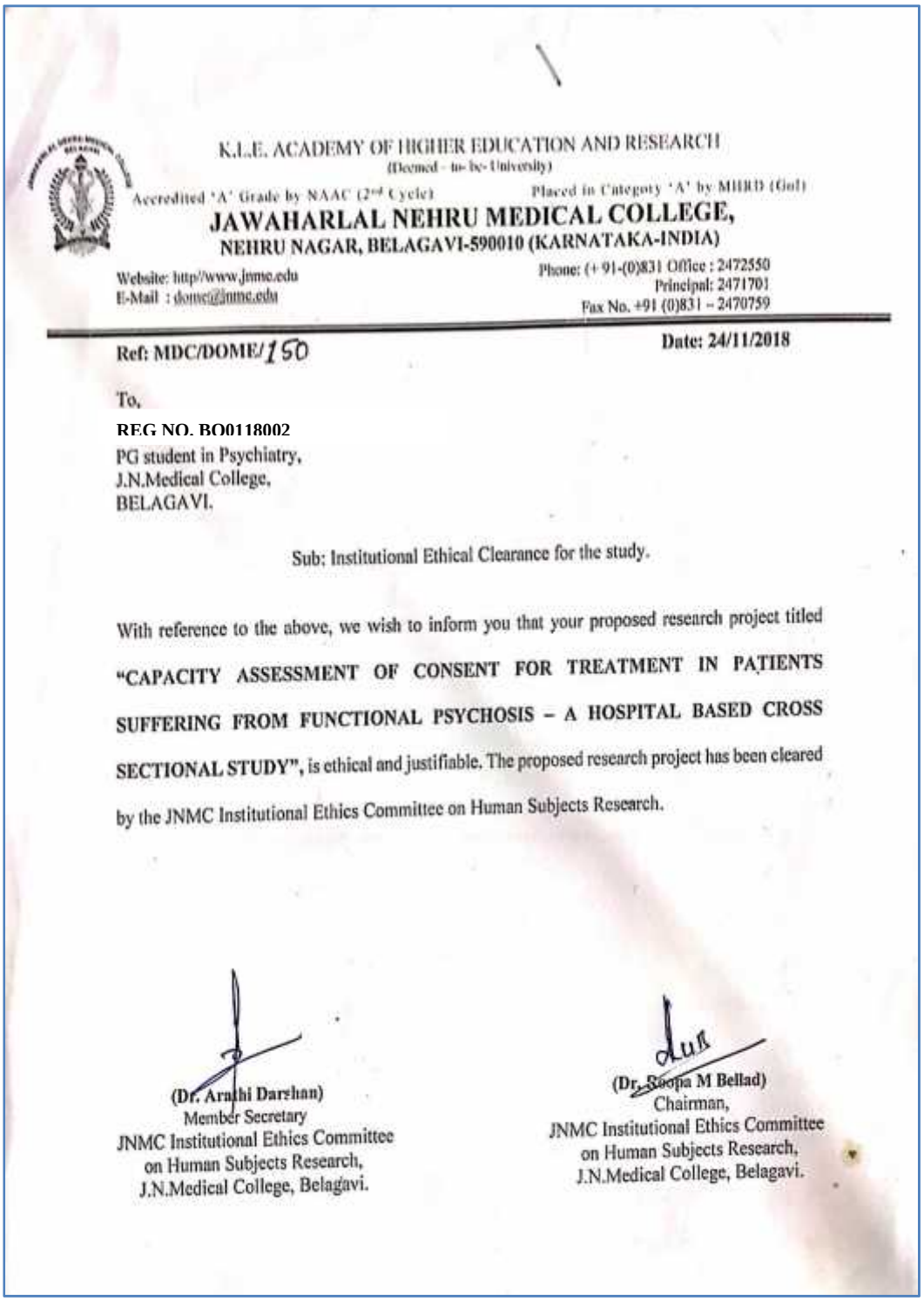
ANNEXURE I

ETHICAL CLEARANCE CERTIFICATE



K.L.E. ACADEMY OF HIGHER EDUCATION AND RESEARCH
(Deemed - to- be- University)
Accredited 'A' Grade by NAAC (2nd Cycle) Placed in Category 'A' by MHRD (GoI)
JAWAHARLAL NEHRU MEDICAL COLLEGE,
NEHRU NAGAR, BELAGAVI-590010 (KARNATAKA-INDIA)
Website: http//www.jnmc.edu
E-Mail : dome@jnmc.edu
Phone: (+91-(0)831 Office : 2472550
Principal: 2471701
Fax No. +91 (0)831 – 2470759

Ref: MDC/DOME/150 **Date: 24/11/2018**

To,
REG NO. BQ0118002
PG student in Psychiatry,
J.N.Medical College,
BELAGAVI.

Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled **"CAPACITY ASSESSMENT OF CONSENT FOR TREATMENT IN PATIENTS SUFFERING FROM FUNCTIONAL PSYCHOSIS – A HOSPITAL BASED CROSS SECTIONAL STUDY"**, is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.

(Dr. Arathi Darshan)
Member Secretary
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

(Dr. Roopa M Bellad)
Chairman,
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

ANNEXURE II

INFORMED CONSENT

Title: "ASSESSMENT OF CAPACITY TO CONSENT FOR TREATMENT IN PATIENTS SUFFERING FROM FUNCTIONAL PSYCHOSIS REQUIRING HOSPITALIZATION IN A TERTIARY CARE PSYCHIATRIC UNIT -A CROSS SECTIONAL DESCRIPTIVE STUDY"

Principal Investigator (PI): REG NO. BQ0118002

Objective/Purpose of the study:

You/your relative are/is being requested to be a subject in a cross-sectional study, the purpose of which is to assess capacity to consent for treatment in patients suffering from functional psychosis requiring hospitalization in a tertiary care psychiatric unit between 1stJanuary 2019 and 31stDecember 2019, by REG NO. BQ0118002, a post graduate student in the Department of Psychiatry at Jawaharlal Nehru Medical College, KAHER, Belagavi, Karnataka.

You/your relative have/has been requested to participate in this study as you/your relative are/is likely to have a psychiatric illness. This study will help to assess the capacity to consent to treatment in patients suffering from psychosis.

Procedure involved: If you/your relative agree to be a part of the study, the PI will interview you/your relative.

Risks and benefits involved: There are no risks involved. During the period of study, the existence or development of any significant findings in terms of psychiatric disorders will be informed by the PI to you/your relative as well as the parent consultant for the appropriate action

Alternatives: Your/your relative's participation in this study is a completely voluntary decision. If you/your relative do/does not want to be a part of the study, you/your relative may refuse for the same or if you/your relative are/is already a part of the study and if you/your relative want/wants to withdraw from the study for any reason, you/your relative may do so without any hesitation. Discontinuation from the study for any reason will not affect your/your relative's current or future relationship with KLES Dr. Prabhakar Kore Hospital, Belagavi.

Privacy and confidentiality: The information provided by you/your relative will be known to the PI and the members of the research team. This information will remain confidential and will be disclosed to others only with your/your relative's written permission or if required by the law.

Financial incentives for participation: You/your relative will not be paid/offered any gifts for participation in the research. There will not be any remuneration for participating in the research and you/your relative will not be reimbursed for any expenses, such as bus/train travelling /companion/assistant etc.

Authorization to publish results: When the results of the research are to be published or discussed in conferences by the PI, no information will be disclosed that will reveal your/your relative's identity.

If you/your relative have/has any questions about this study, you/your relative may contact:

REG NO. BQ0118002

Department of Psychiatry,

Jawaharlal Nehru Medical College,

KAHER, Belagavi-590010

Karnataka.

Dr. _____.

Professor and Head

Department of Psychiatry,

Jawaharlal Nehru Medical College,

KAHER, Belagavi-590010

Karnataka.

STATEMENT OF CONSENT

I have read and have completely understood the entire information given in the consent form, which explains all the details of the study, i.e., the purpose, procedure involved, risks & benefits, privacy & confidentiality, incentives and the authorization to publish the results of the study. I have voluntarily agreed to participate in the study. I may withdraw my participation for any reason or may be withdrawn by the investigator from the study for any reason at any time. I am not giving up any of my legal rights by signing this consent form. I will be given a copy of this consent form.

Signature of the participant with date: _____

Name of the participant: _____

Signature of the authorized representative with date:_____

Name of the authorized representative: _____

Signature of the witness with date: _____

Name of the witness: _____

Signature of the Investigator with date: _____

ANNEXURE II

STUDY PROFORMA

"ASSESSMENT OF CAPACITY TO CONSENT FOR TREATMENT IN PATIENTS SUFFERING FROM FUNCTIONAL PSYCHOSIS REQUIRING HOSPITALIZATION IN A TERTIARY CARE PSYCHIATRIC UNIT -A CROSS SECTIONAL DESCRIPTIVE STUDY"

Date and Time: IP/OP No: Serial No:

Name: Age: Sex: M/F

Religion: Hindu/Muslim/Christian/Others Marital Status/UM/WIDOW

Place: Informant:

Phone No: Socio-economic status:

Diagnosis:

Duration of illness:

Past treatment history:

Present treatment history:

Family history: Y/N

Substance use:

Alcohol Nicotine Cannabis Any other drugs

General Physical Examination:

BP: PULSE: RR: TEMPERATURE:

Height: Weight: BMI:

Systemic Examination:

CNS:

CVS:

RS:

P/A:

Mental Status Examination:

Consciousness

Orientation

Speech

Thought

Mood

Affect

Perception

Insight

Diagnosis

On Application of Scales:

MacCAT-T:

Understanding

Appreciation

Reasoning

Expression of choice

BPRS Score:

Beck's Cognitive Insight Score:

ANNEXURE III

TOOLS

Brief Psychiatric Rating Scale

CLIENT NAME: DATE:
CLIENT IP#:

BRIEF PSYCHIATRIC RATING SCALE (BPRS)

0 = not assessed, 1 = absent, 2 = very mild, 3 = mild, 4 = moderate, 5 = moderately severe, 6 = severe, 7 = extremely severe

1. **SOMATIC CONCERN** Degree of concern over present bodily health. Rate the degree to which physical health is perceived as a problem by the patient, whether complaints have a realistic basis or not. **SCORE** ☐	10. **HOSTILITY** Animosity, contempt, belligerence, disdain for other people outside the interview situation. Rate solely on the basis of the verbal report of feelings and actions of the patient toward others; do not infer hostility from neurotic defenses, anxiety, nor somatic complaints. (*Rate attitude toward interviewer under "uncooperativeness"*). **SCORE** ☐
2. **ANXIETY** Worry, fear, or over-concern for present or future. Rate solely on the basis of verbal report of patient's own subjective experiences. Do not infer anxiety from physical signs or from neurotic defense mechanisms. **SCORE** ☐	11. **SUSPICIOUSNESS** Brief *(delusional or otherwise)* that others have now, or have had in the past, malicious or discriminatory intent toward the patient. On the basis of verbal report, rate only those suspicions which are currently held whether they concern past or present circumstances. **SCORE** ☐
3. **EMOTIONAL WITHDRAWAL** Deficiency in relating to the interviewer and to the interviewer situation. Rate only the degree to which the patient gives the impression of failing to be in emotional contact with other people in the interview situation. **SCORE** ☐	12. **HALLUCINATORY BEHAVIOR** Perceptions without normal external stimulus correspondence. Rate only those experiences which are reported to have occurred within the last week and which are described as distinctly different from the thought and imagery processes of normal people. **SCORE** ☐
4. **CONCEPTUAL DISORGANIZATION** Degree to which the thought processes are confused, disconnected, or disorganized. Rate on the basis of integration of the verbal products of the patient; do not rate on the basis of patient's subjective impression of his own level of functioning. **SCORE** ☐	13. **MOTOR RETARDATION** Reduction in energy level evidenced in slowed movements. Rate on the basis of observed behavior of the patient only; do not rate on the basis of patient's subjective impression of own energy level. **SCORE** ☐
5. **GUILT FEELINGS** Over-concern or remorse for past behavior. Rate on the basis of the patient's subjective experiences of guilt as evidenced by verbal report with appropriate affect; do not infer guilt feelings from depression, anxiety or neurotic defenses. **SCORE** ☐	14. **UNCOOPERATIVENESS** Evidence of resistance, unfriendliness, resentment, and lack of readiness to cooperate with the interviewer. Rate only on the basis of the patient's attitude and responses to the interviewer and the interview situation; do not rate on basis of reported resentment or uncooperativeness outside the interview situation. **SCORE** ☐
6. **TENSION** Physical and motor manifestations of tension "nervousness", and heightened activation level. Tension should be rated solely on the basis of physical signs and motor behavior and not on the basis of subjective experiences of tension reported by the patient. **SCORE** ☐	15. **UNUSUAL THOUGHT CONTENT** Unusual, odd, strange or bizarre thought content. Rate here the degree of unusualness, not the degree of disorganization of thought processes. **SCORE** ☐

7. **MANNERISMS AND POSTURING** Unusual and unnatural motor benavior, the type of motor behavior which causes certain mental patients to stand out in a crowd of normal people. Rate only abnormality of movements; do not rate simple heightened motor activity here. **SCORE**	16. **BLUNTED AFFECT** Reduced emotional tone, apparent lack of normal feeling or involvement. **SCORE**
8. **GRANDIOSITY** Exaggerated self-opinion, conviction of unusual ability or powers. Rate only on the basis of patient's statements about himself or self-in-relation-to-others, not on the basis of his demeanor in the interview situation. **SCORE**	17. **EXCITEMENT** Heightened emotional tone, agitation, increased reactivity. **SCORE**
9. **DEPRESSIVE MOOD** Despondency in mood, sadness. Rate only degree of despondency; do not rate on the basis of inferences concerning depression based upon general retardation and somatic complaints. **SCORE**	18. **DISORIENTATION** Confusion or lack of proper association for person, place or time. **SCORE**

MacARTHUR COMPETENCY ASSESSMENT TOOL FOR TREATMENT (MacCAT-T)

The MacArthur Competency Assessment Tool for Treatment (MacCAT-T) is a copyrighted tool for which permission to use freely was granted on the condition that it will not be used for any other purposes except this study, and that it is not to be freely disseminated. To honour this condition, the scale is not attached published with this dissertation.

Permission Letter:-

Dr. Grover

I've spoken to my co-author of the MaCAT-T and the MacCAT-T's publisher (Professional Resource Press: PRP). We are pleased that you seek to do research on the MacCAT-T with patients in India.

PRP will be willing to send you a copy of the MacCAT-T without charge for use in your research, given your student status and the fact that this is for research purposes. We need a few things from you before we do that.

First, I would like you to acknowledge your agreement that this is for research purposes, not for general clinical use, and that you do not intend to change, modify or translate the MacCAT-T without further approval of the authors and PRP.

Second, please agree that you will keep us informed of the progress and results of your research in the future.

Third, please send me the name/address where we should send the MacCAT-T manual.

Regards,

Thomas Grisso, Ph.D.
University of Massachusetts Medical School

Beck's Cognitive Insight Scale

Figure 2. Beck Cognitive Insight Scale (BCIS)

	Do not agree at all	Agree slightly	Agree a lot	Agree completely
Self-reflectiveness				
1. At times I have misunderstood other people's attitudes towards me				
3. Other people may be more objective about the cause of my unpleasant experiences than I am.				
4. I have jumped to conclusions too fast.				
5. Some of may experiences that seemed very real may have been due to my imagination.				
6. Some of the ideas that I was certain were true turned out to be false.				
8. Even though I feel strongly that I was right I could be wrong.				
12. If somebody points out that my beliefs are wrong I am willing to consider it.				
14. There is often more than one possible explanation for why people act the way they do				
15. My unusual experiences may be due to me being extremely upset or stressed.				
Self-certainty				
2. My interpretations of my experiences are definitively right.				
7. If something feels right, it means that it is right.				
9. I know better than anyone else what my problems are.				
10. When people disagree with me, they are generally wrong.				
11. I cannot trust other people's opinion about my experiences.				
13. I can trust my own judgement at all times.				