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MEDICAL DECISION-MAKING CAPACITY AMONG GERIATRIC PATIENTS WITH AND WITHOUT DEMENTIA

– COMMUNICATION-BASED APPROACHES FOR ASSESSMENT AND FACILITATION

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Stockholm 2019

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Published by Karolinska Institutet
Printed by E-Print AB 2019

ISBN 978-91-7832-356-3

Medical decision-making capacity among geriatric patients with and without dementia
– communication-based approaches for assessment and facilitation

THESIS FOR DOCTORAL DEGREE (Ph.D.)

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Till mina barn, Edvin, Ellie och Hillevi,
som har gett mig mer kärlek än jag trodde var möjligt, och lärt
mig saker om livet som jag inte visste att jag behövde veta.

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POPULÄRVETENSKAPLIG SAMMANFATTNING

Det övergripande syftet med denna avhandling är att undersöka medicinsk beslutsförmåga hos geriatriska patienter med och utan demenssjukdom. Hos personer med demenssjukdom förekommer ofta en nedsatt förmåga att fatta beslut i medicinska kontexter, orsakad av de kognitiva svårigheter som är kärnan i diagnosen.

Äldre personer är en utsatt grupp när det gäller att fatta självständiga beslut i medicinska sammanhang. Att uppmärksamma vilka personer som behöver stöd för att kunna fatta egna, välgrundade beslut är viktigt för att främja patienters delaktighet, men också för att kunna skydda de individer som saknar beslutsförmåga, exempelvis genom att engagera ställföreträdare.

Att fatta välgrundade, självständiga, beslut kräver flera olika språk- och tankemässiga förmågor: du måste förstå informationen som ligger till grund för beslutet, du behöver väga för- och nackdelar mot varandra, och slutligen behöver du uttrycka ditt beslut på ett förståeligt sätt till omvärlden. Beslut inom vården är ofta svårare att fatta än mer vardagliga beslut, eftersom informationen som ligger till grund för beslutet ofta innehåller medicinska termer som gemene man inte känner till. Informationen är ännu mer komplex när det handlar om att delta i en medicinsk forskningsstudie.

Studierna i avhandlingen innefattar två olika typer av beslutsprocesser: 1) att bestämma sig för att delta i en medicinsk forskningsstudie eller inte, och 2) att delta i ett vårdplaneringsmöte på en geriatrisk vårdavdelning.

I första studien användes metoden *Samtalsmatta* i ett försök att förbättra kommunikationen under vårdplaneringar, men resultaten visade inte på någon förbättring. I andra studien undersöktes om *Språkligt målgruppsanpassad information* kunde underlätta ställningstagande till att delta i ett forskningsprojekt för patienter som var i ett tidigt skede av Alzheimers sjukdom. Den medicinska beslutsförmågan var dock oförändrat låg.

Tredje studien konstruerade och presenterade egenskaper hos ett nytt test: *Kliniskt instrument för medicinsk beslutsförmåga*. Det är ett snabbt test som indikerar om en patient har nedsatt beslutsförmåga att fatta ett välgrundat beslut gällande att delta i medicinska forskningsprojekt. Fjärde studien använde sedan detta test för att undersöka hur vanligt det var med nedsatt medicinsk beslutsförmåga hos inneliggande geriatriska patienter utan demenssjukdom. Resultaten visade att en majoritet hade problem att fatta denna typ av beslut. Det är därför av intresse att följa upp detta med att undersöka förekomsten av nedsatt medicinsk beslutsförmåga hos ytterligare patientgrupper.

I slutet av avhandlingen presenteras ett förslag på hur forskare i rekryteringsprocessen av deltagare på ett systematiskt sätt kan efterfråga samtycke från en geriatrisk patient. I fortsatt forskning vore det intressant att utvärdera om detta flödesschema kan främja ett mer patientsäkert tillvägagångssätt.

ABSTRACT

Introduction: Medical decision-making capacity concerns a patient's cognitive abilities to make autonomous decisions regarding own person in medical contexts such as to choose treatment or accept/decline participation in research projects. Cognitive communicative functions are needed in order to process information, reach a decision and articulate it. Communication within medical decision-making processes requires receptive, cognitive communicative and expressive language skills.

The overall aim of the thesis is to investigate medical decision-making capacity using communication based approaches to facilitation and assessment in geriatric patients with and without dementia.

Methods: *Study I* investigated whether participants at discharge planning meetings perceived better communication function in geriatric patients with cognitive impairment who had been prepared using the Talking mats method. *Study II* examined if medical decision-making capacity improved among patients with Alzheimer's disease if written participant information were presented as linguistically adapted, more readable vignettes. The medical decision-making capacity was measured by *Swedish linguistic instrument for medical decision-making*. *Study III* developed a new test to assess medical decision-making capacity: *Clinical instrument of medical decision-making capacity*. The test was validated by comparing results between three groups: patients with Alzheimer's disease, patients with Mild cognitive impairment and healthy controls. Test scores were compared to test results on designated linguistic and cognitive tests. *Study IV* used *Clinical instrument of medical decision-making capacity* to investigate the prevalence of impaired medical decision-making among geriatric in-patients without known cognitive impairment.

Results: Neither Talking mats nor Adapted vignettes was found to improve geriatric patients' ability to participate in the specified medical decision-making processes. *Clinical instrument of medical decision-making capacity* showed good test properties. Positive correlations were found between preserved medical decision-making capacity and longer formal education, well-functioning overall cognition, high premorbid cognitive function, and scores on specific tests assessing e. g. comprehension and vocabulary. An unexpected finding was that the prevalence of impaired medical decision-making capacity was as high among in-patients with somatic conditions as among out-patients in early stage of Alzheimer's disease.

Conclusions: Medical decision-making processes are difficult to participate in not only for patients with dementia but also for in-patients, regardless of whether a neurodegenerative process is present or not. A flow-chart was constructed from a cognitive communicative perspective. The purpose was to suggest a standardized way to promote the best possible participation and obtain the most accurate perception of the patient's wishes when asking geriatric patients for informed consent.

LIST OF PUBLICATIONS

This thesis is based on the following studies, which will be referred to in the text by Roman numerals:

I. **Thalén, L.**, Almkvist, O. & Tallberg, IM. (2016) How do patients with cognitive impairment communicate during discharge meetings? Evaluation of participation using Talking mats. *Journal of Speech Pathology and Therapy* 2016;1(1):e1000106

II. **Thalén, L**., Heimann Mühlenbock, K., Almkvist, O., Eriksdotter, M., Sundström E. & Tallberg IM. (2017) Do adapted vignettes improve medical decision-making capacity for individuals with Alzheimer's disease? *Scandinavian Journal of Psychology* 2017;58(6):497-503

III. **Thalén, L**.*, Stormoen, S.*, Almkvist, O., Eriksdotter, M., Heimann Mühlenbock, K., Sundström E. & Tallberg, IM. A simple tool to detect impaired medical decision-making capacity for research settings (**submitted**) *shared first authorship.

IV. **Thalén, L**. & Tallberg, IM. A majority of in-ward, geriatric patients might have impaired medical decision-making capacity (**submitted**)

LIST OF ABBREVIATIONS

ACED	Assessment of capacity for everyday decisions
AD	Alzheimer's disease
BeSS	Test battery of high-level language functions
CCTI	Capacity to consent to treatment interview
CG	Control group (patients)
DLS	Diagnostic material for analysis of reading and writing skills
HCG	Healthy control group
KIMB	Clinical instrument of medical decision-making capacity
LIMD	Swedish linguistic instrument for medical decision-making
MacCAT-CR	MacArthur competence assessment tool for clinical research
MacCAT-T	MacArthur competence assessment tool for treatment
MCI	Mild cognitive impairment
MDC	Medical decision-making capacity
MMSE	Mini-mental state examination
MOCA	Montreal cognitive assessment
RAVLT	Rey auditory verbal learning test
ROC	Receiver operating characteristic
SVIT	Sentence structure, vocabulary load, idea density, human and personal interest
TMG	Talking mats group
UBACC	University of California brief assessment of capacity to consent
VAS	Visual analogue scale

Definitions of phrases

Medical decision-making capacity: The cognitive ability an individual has to make an autonomous decision in a medical context.

Medical decision-making process: The process to reach a decision within medical contexts, which involves an individual's capacity but also the situation and the person asking for a decision.

AIMS OF THESIS

The overall aim is to investigate medical decision-making capacity in geriatric patients with and without dementia. Communication-based approaches are used to examine two methods for facilitation, and assessment of capacity to give informed consent.

The main aim of each study included is:

- Compare the perceptions of patients, family members, nurses and social care workers concerning patients' communication in discharge planning meetings depending on whether geriatric in-patients with cognitive impairment are prepared using Talking mats or not.

- Investigate whether use of linguistically adapted vignettes yields any improvement in medical decision-making capacity among patients with Alzheimer's disease.

- Develop and validate a written, vignette-based test to detect impaired medical decision-making capacity among patients with Alzheimer's disease and Mild cognitive impairment.

- Investigate the prevalence of impaired medical decision-making capacity among geriatric in-patients without dementia or acute confusion.

OUTLINE OF THESIS

The background centers around medical decision-making capacity in geriatric patients. A communicative base is used to describe and compare different aspects of medical decision-making capacity, including patient participation and health literacy. Based on the four cognitive components that medical decision-making capacity is described as consisting of, tests that assess medical decision-making capacity are outlined together with various conditions in the geriatric population which can affect medical decision-making capacity. Approaches to support geriatric patients in medical decision-making processes are described.

The thesis examines medical decision-making from two different aspects: facilitation and assessment. The *Talking mats* method is used in an attempt to support communication and participation in discharge planning meetings for patients with dementia or other documented cognitive impairment. *Adapted vignettes* is used for patients with Alzheimer's disease in an attempt to increase medical decision-making capacity regarding giving informed consent.

The second aspect focuses on assessing medical decision-making capacity. A test called *Clinical instrument of medical decision-making capacity* (KIMB) is constructed and validated among patients with and without dementia, as well as healthy controls. Finally, KIMB is used to examine the prevalence of impaired medical decision-making capacity among geriatric in-patients with somatic illnesses.

The sections Methodological considerations and Integrated results present the included studies briefly, highlighting similarities and differences. In the concluding Discussion, the ethical dilemma concerning promoting autonomy and need to protect patients who lack medical decision-making capacity, is highlighted based on two important conclusions: geriatric in-patients are at risk of impaired medical decision-making capacity regardless of whether dementia is present or not; and increasing capacity using communicative and/or cognitive support may prove difficult. Figure 1 shows a flow-chart of the working process for the thesis.

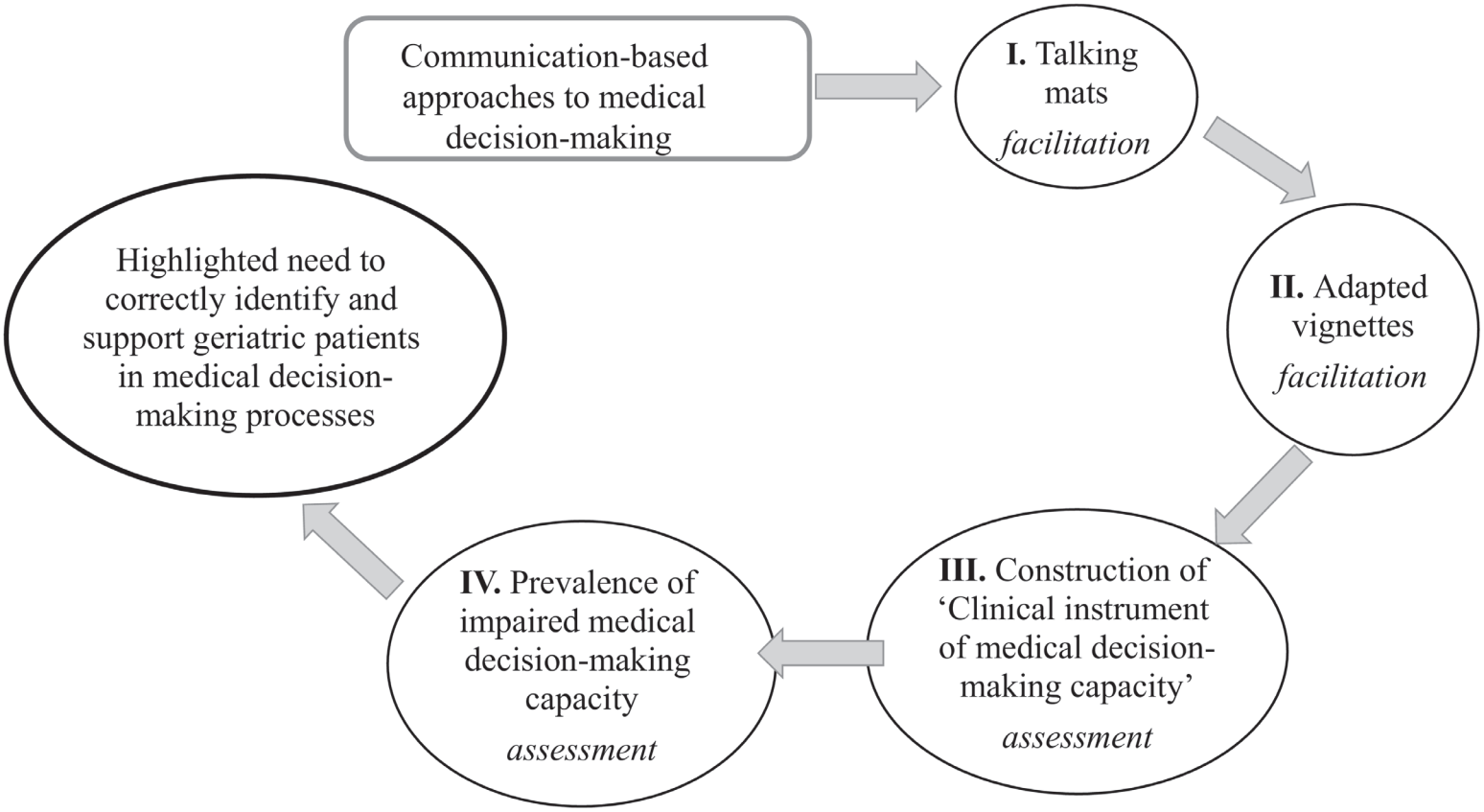


Figure 1. Working process for the thesis, *Medical decision-making capacity in geriatric patients with and without dementia – communication-based approaches to assessment and facilitation*.

1 BACKGROUND

1.1 OVERVIEW OF THE GERIATRIC POPULATION

Communication in medical decision-making requires receptive, cognitive communicative and expressive language skills. Receptive language skills are fundamental to participation in medical decision-making. Understanding information is the first requirement before processing the information. Cognitive communicative skills are needed to evaluate and apply the information to one's own situation. Expressive language skills are needed to communicate a choice, but also in order to give information to health care personnel, for example regarding symptoms. In most circumstances, medical decision-making capacity is regarded as a continuum, not a dichotomous function which either exists or not; different decisions are more or less complex and therefore place higher or lower demands on higher cognitive functions.[1] The following conditions are relatively prevalent among geriatric patients and can affect communication and ability to participate in medical decision-making processes negatively.[2,3]

Cognitive communicative disorders (CCD) include all communicative disorders which are caused by cognitive impairment, including Mild cognitive impairment, dementia and other neurodegenerative disorders.[4] From the perspective of CCD, a person's ability to produce and understand speech reflects his/her cognitive capacities. Different parts of the brain may be affected by disease, and result in different cognitive symptoms and impairment of specific language and communicative abilities.[5] Whenever cognitive functions are temporarily or permanently affected, a warning flag should be raised regarding possible communication difficulties and impaired medical decision-making capacity.

Alzheimer's disease (AD) is a primary neurodegenerative disease which impairs a person's capacity to manage everyday living activities independently. The disease has an insidious onset, and progresses over time. Problems with memory are a core criterion, but other cognitive functions are also affected. Difficulties regarding linguistic abilities include for example finding words, understanding and struggling with writing. Communicative skills have been highlighted as an important factor in maintaining quality of life and participation in daily activities.[6] Complex tasks and reasoning are more difficult than concrete tasks for patients with AD. Impaired visuospatial abilities are common. Besides cognitive impairment, changes in behavior and personality can emerge, such as decreased motivation or increased tendency to withdraw socially.[7,8]

Mild cognitive impairment (MCI) is a condition that is manifested by different cognitive symptoms in an individual, but does not fulfil the criteria for dementia. Diagnostic criteria for MCI include subjective complaints of declining cognitive functions and impaired cognitive functions shown by objective assessment. However, global cognitive function and ability to

perform activities of daily living are preserved.[9] Patients with MCI are at heightened risk of developing AD.[10-12]

Multimorbidity in a patient has been defined in different ways, but the two most common are *two or more chronic conditions present or three or more chronic conditions present*. Several definitions include age criterion of ≥ 65 years, while others set the limit to 75 years or older. The diversity of definitions complicates efforts to compile data on the prevalence and consequences of multimorbidity.[13]

As for multimorbidity, *frailty* has been defined and operationalized in several ways.[14] Simplified, frailty describes the degree to which aging has impaired a person's physical, psychological and social function,[15] or as an age-related syndrome that affects a patient's capability to manage external stressors.[16] Attempts have been made to define subgroups within the otherwise heterogenic group of patients.[17] Frailty increases risk for cognitive impairment, and vice versa.[14,16,18-22] Since both frailty and cognitive decline are linked to aging, the term *cognitive frailty* have been introduced.[14,18]

1.2 MEDICAL DECISION-MAKING CAPACITY

1.2.1 Definition

Medical decision-making capacity (MDC) concerns a patient's cognitive abilities to make decisions regarding own person in medical contexts. MDC is a complex cognitive function, relying on, for example, abilities to: understand information; ponder a future, hypothetical situation; evaluate different choices; reason regarding risks and benefits; make a choice; and communicate it in an intelligible way.[23,24] While the terms are sometimes used interchangeably, MDC should not be confounded with medical decision-making *competency*, which regards legal standards and is a juridical status a person can be deprived of within the legal system. Co-existing terms for MDC are healthcare consent capacity and healthcare decision-making capacity.[25] Different terms are used to specify what type of decision at stake: "capacity to consent to treatment" indicates that the decision takes place within routine medical care,[26] while "informed consent capacity" and "research consent capacity" signal that the decision at hand regards participation in research.[27] In this thesis, the term MDC is used consistently.

1.2.2 The four-component model

MDC was originally discussed in ethical and legal terms: an individual must be competent to make decisions within medical contexts. At the end of the 20th century, researchers agreed to describe MDC according to a cognitive four-component model. Focus was on *understanding, appreciation, reasoning* and *expression of a choice*, which were considered essential parts of a well-founded decision.[28,29] All four components must be present for a person to be regarded as having a valid MDC. The baseline in the model is

to *understand* the information the decision should be based on. *Appreciation* means that a patient should exhibit the capability to apply the information to his/her own situation. The component *reason* focuses on the person's ability to compare the risks and benefits of different alternatives in a rational and logical way. Finally, a patient should be able to express his or her choice in an unambiguous way.[26,30] The four-component model is predominant in research aiming to find predictors for MDC.[25]

Studies regarding which cognitive functions contribute to MDC are not conclusive. It has been emphasized that MDC relies on multifaceted multi-domain cognitive functions.[31,32] Possible explanations for the diverse research results are that: 1) several definitions of MDC exist; 2) the tests used to assess MDC also differ; 3) correlations to MDC have been investigated using extensive neuropsychological test batteries without specific hypotheses,[25,33,34] and using stepwise regression, which may be an inappropriate basis for making deductions about correlations.[35] Cognitive functions which have been described as explaining impaired MDC include cognitive communicative functions such as verbal reasoning,[31] verbal memory,[31,36] verbal fluency[37] and confrontational naming.[38] A review regarding future thinking in dementia concluded that deficits in episodic memory, semantic memory and executive functions contribute to impairment.[39] Overall cognitive deficits show correlation to impaired MDC, as well as large intra-test variability between test-sessions.[33]

Whilst there is a justified demand for specificity regarding definition and assessment in MDC in order to better understand its neuropsychological attributes, the four-component model has been criticized due to its narrow focus on cognition.[25,34] Intra-personal factors besides cognition that can contribute to MDC include a person's beliefs, values, emotions[40-42] and measures of insight.[43,44] Standardized tests for MDC, however, only assess cognitive functions.

1.2.3 Assessing medical decision-making capacity in geriatric patients

The first factor when considering whether to assess MDC is patients and their conditions. Adults are assumed to have unimpaired MDC unless otherwise indicated, but this may be an over-simplification for the geriatric population. Among very old individuals in senior housing facilities, even subtle cognitive decline was shown to affect their MDC.[45] Conditions where a non-negligible number of affected patients have impaired MDC (temporarily, declining or permanently) are for example neurodegenerative diseases like AD and Parkinson's disease,[44,46-49] certain psychiatric disorders[50] and traumatic brain injury.[51] A majority of patient – caregiver encounters in clinical work or medical research do not involve explicit assessment of MDC.[52] A clinician or researcher accepting a patient's choice has, however, implicitly accepted the patient's MDC as adequate. When a patient presents with any disease known to affect cognition or communication, assessment of MDC should be considered.[29]

Semi-structured interviews are a clinical approach to formalize assessment of MDC. The interviews include open-ended, specific, questions regarding the decision to be made. The questions address at least one, but may include all four components of MDC. A semi-structural approach regards a specific decision at hand. The first question should probe the patient's understanding. Any misunderstanding should be corrected before proceeding with questions regarding decision and reasoning. Worth noting is that semi-structured interviews include a teach-back procedure, thus tending toward facilitation of the patient's understanding rather than pure assessment of his/her MDC. Performing a semi-structured interview can increase interrater agreement as compared to relying entirely on clinicians' subjective opinions regarding patients' MDC.[29]

The most comprehensive level for assessing MDC uses standardized tests. The assessments commonly include information, a standardized interview and scoring. Validation of tests assessing MDC struggles with the fact that even though all tests are based on one, several or all four cognitive components, correlations to clinical judgment of patients' MDC are low.[53] Test constructors have used the non-congruent results to argue the need for standardized protocols, while others have raised the question of whether the tests really are valid to assess MDC.[25,54,55] The definition of MDC was originally developed from definitions of juridical competence and a theoretical line of argument regarding what capacities it is reasonable to assume are a valid part of MDC. The construct validity itself of the concept MDC is therefore not self-evident. Consequently, comparing existing tests is not simple. A Cochrane review of tests that assess MDC was later withdrawn, due to the lack of a consistent definition.[56,57]

Existing tests concern decisions relating to either treatment or research, both types assess an overall MDC based on a hypothetical situation or a specific decision in real life. In Figure 2, existing tests are plotted with regard to whether the test uses the vignette method or a real-life decision, and whether it assesses informed consent to medical research or regular treatment decisions. All tests included have been developed for and/or validated in a geriatric population.[25,54]

When assessing a potential participant's capacity to give informed consent the vignette method is typically utilized, where written and verbal information regarding a hypothetical clinical trial is presented. Immediately afterward, a standardized interview is carried out to assess MDC. The interviews are transcribed and/or scored according to the test's protocol.[58,59] Tests using the vignette method exist in several languages, with MacArthur competence assessment tool for clinical research (MacCAT-CR) as the most widely used test.[25,54,60,61]

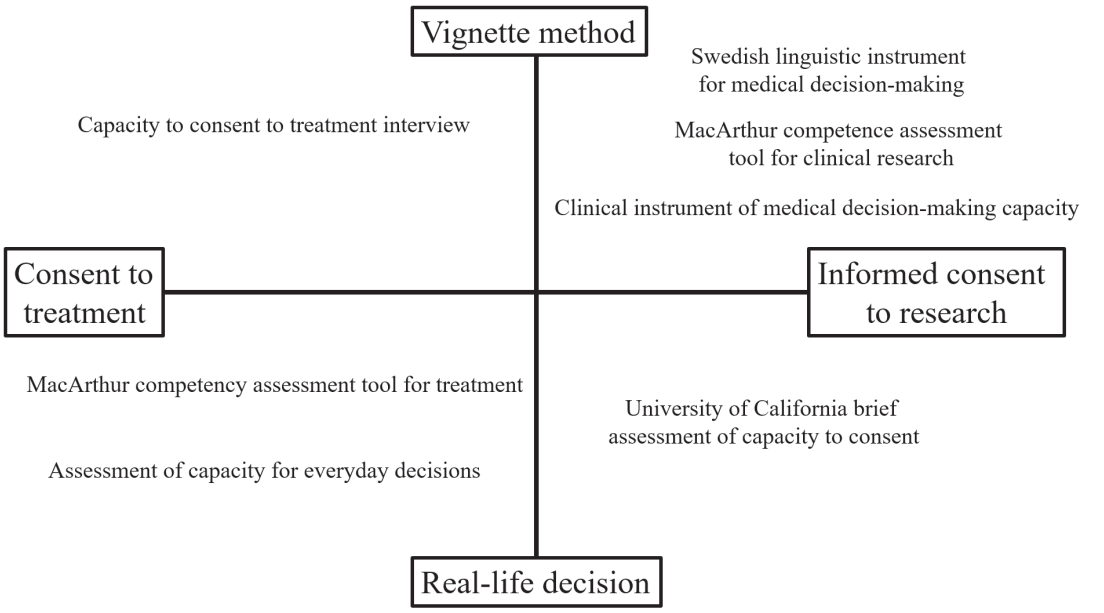


Figure 2. An overview of tests measuring medical decision-making capacity.

MacCAT-CR consists of a vignette and a standardized interview assessing the original four components of MDC, with an emphasis on understanding (13 questions) followed by appreciation (three questions), reasoning (four questions) and expressing a choice (one question). The test takes approximately 20 minutes to complete. Sub-scores and a total score are obtained, but there is no cut-off score indicating if a patient has impaired MDC.

Swedish linguistic instrument for medical decision-making (LIMD) assesses capacity to give informed consent. The original four components of MDC were merged to three: 1) comprehension (*understanding*), 2) evaluation (combining *appreciation* and *reasoning*) and 3) intelligibility (*expression of a choice*). The aim was to exclude a subjective opinion whether a patient's reasoning was logical or not, and instead add focus on linguistic factors in the participants responses. Necessary linguistic abilities include receptive language and ability to express oneself, but cognitive abilities are also important, e.g., in order to reason and compare risks versus benefits. The original study included three vignettes with information about hypothetical drug trials with different levels of potential risks and benefits. LIMD is an extensive and time-consuming test; each vignette first is read aloud, followed by a standardized interview, verbatim transcription and scoring. LIMD's primary use is when an in-depth assessment is warranted in research.[24] Given the cumbersome nature of existing tests regarding capacity to give informed consent, there was need for a more user-friendly test.

Clinical instrument of medical decision-making capacity (KIMB) was specifically constructed to be fast and easy to use. KIMB is purely text-based, in contrast to MacCAT-CR and LIMD, which contain standardized interviews. The vignette concerns a hypothetical

clinical trial. The text has 13 embedded tasks assessing reading comprehension. The vignette is followed by a multiple-choice questionnaire which assesses comprehension, evaluation and choice. KIMB contributes to and complements previous tests assessing capacity to give informed consent with its features: 1) being fast to complete, 2) using the vignette method, 3) including a fictitious person in the hypothetical vignette. The test construction is thoroughly described in *Methodological considerations*.

In contrast to the above-mentioned tests that utilize the vignette method, the University of California brief assessment of capacity to consent (UBACC) uses a specified protocol that needs to be adapted to each specific situation. The questionnaire does not require the patient to express an intelligible choice, but includes a teach back process to correct any misunderstanding.[62-64] It could therefore be argued that UBACC accesses the best available decision rather than purely assessing capacity to give informed consent. The test can be completed in just five minutes.

Among tests which regard treatment decisions, the MacArthur competence assessment tool for treatment (MacCAT-T) is similar to its equivalent MacCAT-CR. A structured interview approach is used to assess MDC, typically within 20 minutes. Unlike MacCAT-CR, where a hypothetical vignette is used, MacCAT-T incorporates the information and decision at hand for the patient.[26] Assessment of capacity for everyday decisions (ACED) has a functional and specific focus on patients' decision-making capacity regarding activities of daily living. A structured interview with written information is performed, and the score is presented in six sub-areas.[43] In contrast to MacCAT-T and ACED, which both use information concerning a real-life situation for the patient, the Capacity to consent to treatment interview (CCTI) utilizes the vignette method with two hypothetical treatment decision as written fundament, followed by a standardized interview. The score is expressed in terms of adherence to five legal standards. CCTI can be completed within 25 minutes.[65]

1.2.4 The impact of cognitive impairment and other intra-personal factors

MDC is typically affected negatively already in mild to moderate stages of AD.[24,32,65-69] Problems arise particularly in the contexts of understanding, reasoning and appreciating,[37,65,70] but also in evaluating risks and benefits and expressing a decision.[24] Examples of cognitive communicative capacities affected in early stages of AD are abstract thinking, reasoning and using figurative language. These capacities are needed to comprehend and make informed medical decisions, but also to imagine what consequences different decisions have.[71,72] The cognitive communicative problems that accompany with AD probably affect the possibility of successfully carrying out a standardized assessment of MDC. Reduced reading ability may contribute to impaired MDC, especially regarding informed consent where the information is extensive.[73-76] While individuals with AD have impaired MDC early on, exceptions do exist where individuals with AD are still able to give informed consent.[33]

Pragmatic communication problems, possibly due to impairment in working memory, episodic memory and attention problems, also arise during the course of AD. The pragmatic difficulties manifest for example in repeated questions and misunderstandings.[76-78] The more complex the information, the more difficulties a patient with AD will have perceiving it.[76] Inference – the ability to draw conclusions from information received – deteriorates, which hinders the patient from reasoning and appreciating information related to the decision that is to be made. Anomia in AD results in circumlocutions and the tip of the tongue phenomenon.[79] Together, the various communicative difficulties realized in AD make it hard for the communication partner to understand what the individual wants to express.[78,80]

Patients with MCI do not exhibit as impaired MDC as patients with AD. Nevertheless, on a group level, impaired MDC has consistently been found.[24,81,82] A three-year follow up comparing patients with MCI and healthy controls showed at baseline that appreciation, reasoning and understanding were significantly lower within the MCI group. After three years, the MCI group showed a significant decline in understanding. The decline was most prominent for individuals who had had their diagnosis converted to AD.[67]

Advanced age is a joint risk-factor for multimorbidity and cognitive impairment alike.[83] Patients with AD have been reported to have at least one comorbidity in 94% of the cases.[84] Studies have either taken the approach that dementia increases risk for multimorbidity,[85] or the other way around.[86] The relationship between dementia and multimorbidity is complex.[87] Additive as well as interactive effects have been suggested between co-occurring cognitive impairment and multimorbidity,[88] resulting in for example accelerated decline in ADL[89] and worse day to day functioning.[90] Cerebrovascular diseases have been reported to especially increase risk for impaired cognitive functions.[91] Somatically ill in-patients without cognitive impairment have also been found to have impaired MDC.[52,92,93]

Intra-personal factors which have been observed are a patient's beliefs and values, authenticity, emotions[40-42] and measures of insight.[43,44] External factors include the person who asks for a decision, and the situation in which the decision-making is taking place,[94] including time.[45] Since factors outside the patient can more readily be altered, the external factors are important when studying different approaches to support patients in the decision-making process.

MDC as a concept presupposes a desire for and from a patient to make an autonomous decision. However, a decision is always made in a context. Patients may invite others to discuss the matter prior making an important decision. As situations change, decisions may change. The inverse is also true; a new decision changes the situation and adds new experiences and factors, which in turn can affect decisions later on.[94] The next section will discuss medical decision-making from a complementing perspective – patient participation.

1.3 PARTICIPATION IN MEDICAL DECISION-MAKING PROCESSES FOR GERIATRIC PATIENTS

1.3.1 Communicative aspects of participation in medical contexts

Factors influencing geriatric patients' opportunities to actively participate in medical decisions can be viewed from three perspectives: patient-related factors, factors associated with the health care setting/situation, and factors related to health care provider.[94]

There is no standardized, coherent method for examining patient participation. As with MDC, the diverse measures make it difficult to draw conclusions and compare results between studies.[95,96] Well-functioning communication is, however, a recurring aspect. A review divided factors that affect patient participation into three different categories: the relation and communication between patient and caregiver, environmental factors (e.g. time) and last but not least, the need to acknowledge the patients' awareness of his/her situation together with his/her values.[97]

Well-functioning communication, including that information is presented in an understandable way, is often emphasized as a major factor and prerequisite for any patient participation.[2,97,98] The desire to be well-informed is highlighted as being important to many geriatric patients.[99-101] Getting information in an understandable way, and having good communication with care providers,[100] including a trustful relationship, are other important factors.[99,102,103] Communicative skills in healthcare staff have been emphasized as an important factor to involve patients in medical decision-making processes.[2,98,100] Conversely, communication barriers, such as stressed caregivers and lack of shared language with the patient on the other hand hinder participation.[2,99,104]

The term *health literacy* originates from epidemiologic rather than cognitive research. Health literacy involves cognitive functions like ability to read, understand texts and numbers in a medical context and evaluating this information with regard to one's own situation. However, intra-personal factors besides cognition are also involved. Knowledge and motivation also affect decisions in medical contexts, including disease prevention, self-care management, health promoting behaviors and access to health care platforms.[105-108] Health literacy has been described to exist at different levels, where functional literacy is the fundamental skill of reading and writing, followed by the higher level of communicative literacy where the abilities can be used to apply information to different situations, and finally critical literacy, where information can be scrutinized critically.[109]

In a survey from Europe, almost half of 8000 citizens from eight different countries showed an "insufficient" or "limited" level of health literacy. Poor health literacy was associated to several socio-demographic factors such as low income, low social status, low education and

old age.[110] Lower compliance to medical treatments, worse treatment outcomes and poor adherence to self-care are other outcomes associated with low health literacy.[107,108]

The extent to which a geriatric patient desires to have an autonomous, active role in health care decisions is individual.[99,100,102,111-114] Geriatric patients may prefer to make a decision together with either formal or informal caregivers, or wish that the decision is made by caregivers who have the medical competency. However, other studies have highlighted that even among the oldest old patients, some desire to participate, but that actions to facilitate communication may be needed to enable their participation.[115] A thesis concluded that a majority of geriatric patients desire an active role in medical decision-making. Factors that hindered participation were found in organizational structures that affected the formal caregivers' opportunities to make a holistic assessment of patients, and the amount of time available at the hospital.[103]

The organizational context of health care can also affect staff, which in turn may affect patient's participation negatively, for example if the formal caregiver experiences stress due to limited resources or time. Environmental factors such as busy surroundings or interruptions can also have an adverse effect on participation. Meeting a large number of formal caregivers has been reported to influence participation negatively.[2,104,116]

Geriatric patients' participation has positive side-effects. Patients express greater satisfaction with care provided,[97] increased trust in health care staff, and more positive and direct communication. Enhanced adherence to treatment and personal motivation to improve health, together with better health and quality of life have also been reported.[2,97]

1.3.2 Participation in discharge planning meetings

Until recently, discharge planning meetings were standard at Swedish geriatric wards prior discharge of a patient. The aim was to ensure continued care at an appropriate level, whether at home or at another care facility. In autumn 2018, the legislation was changed and discharge meetings were replaced by Coordinated Individual Plans (in Swedish: *Samordnad individuell vårdplan*), which are typically created outside the hospital, after discharge. Since this change took place at the very end of this doctoral project, the focus within the thesis summary is still discharge meetings.

Two major factors are highlighted in the literature regarding geriatric patients' participation in discharge meetings: patients' preferences and communication. The patient needs to feel included and listened to, but the importance of attitudes, knowledge and skills of staff, as well as the environmental setting, were highlighted in a review.[2] Figure 3 illustrates facilitators of well-functioning communication and participation in discharge meetings, arranged according to whether they are applied before or during the meeting.

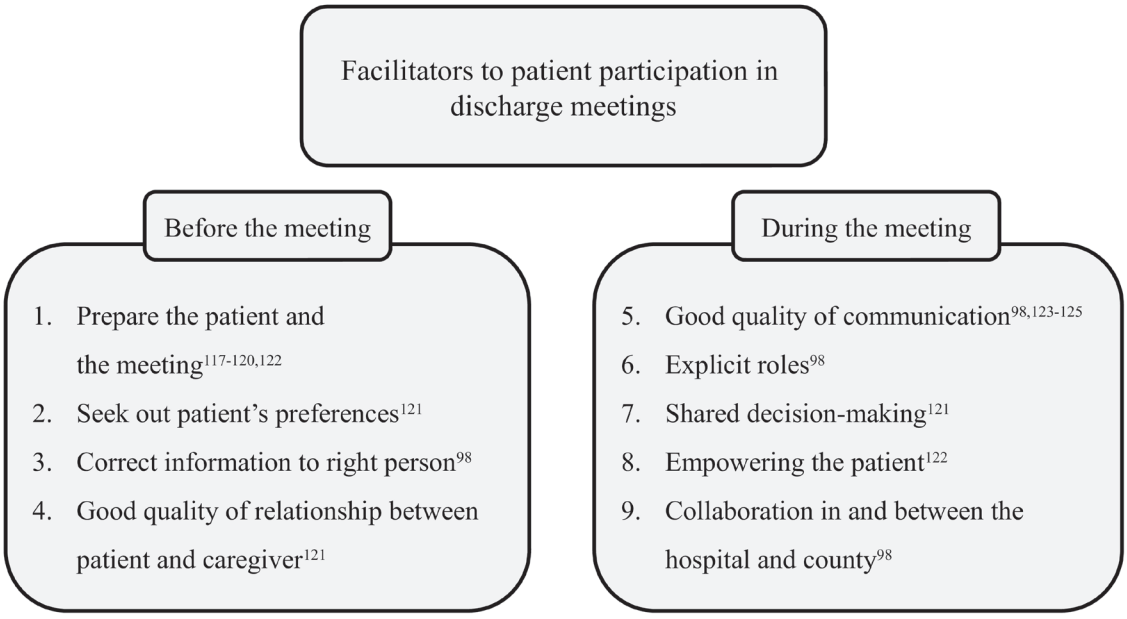


Figure 3. Identified key factors in communication which can act as facilitators of patient participation in discharge planning meetings.

Factors listed under Before the meeting in Figure 3 aim to increase patient participation during the meeting. Several studies have highlighted the importance of preparing the patient prior the discharge meeting. It may seem obvious that the patient should be prepared before the meeting, but this is not always done.[117-120] The patient needs to know the aim and general outline of the discharge meeting.[98,121,122] Communication is needed within the hospital, between patient and caregiver and within the team caring for the patient, but also with external stakeholders like representatives from the municipality and, if applicable, the patient's family.[98] Quality of communication during discharge meetings has been highlighted as crucial for patient participation in several studies.[123-125]

1.4 COGNITIVE COMMUNICATIVE APPROACHES TO SUPPORT GERIATRIC PATIENTS IN MEDICAL DECISION-MAKING PROCESSES

The structured methods to facilitate geriatric patients' participation in medical decision-making processes can be divided into three categories depending on who or how the method is intended to support or facilitate: 1) support the patient, 2) facilitate the situation and 3) enhance caregiver's communicative skills. Facilitating the caregiver's skills will not be addressed here, since it is not a method used within this thesis. Figure 4 shows a three-way perspective on factors influencing geriatric patients' participation in medical decision-making processes.

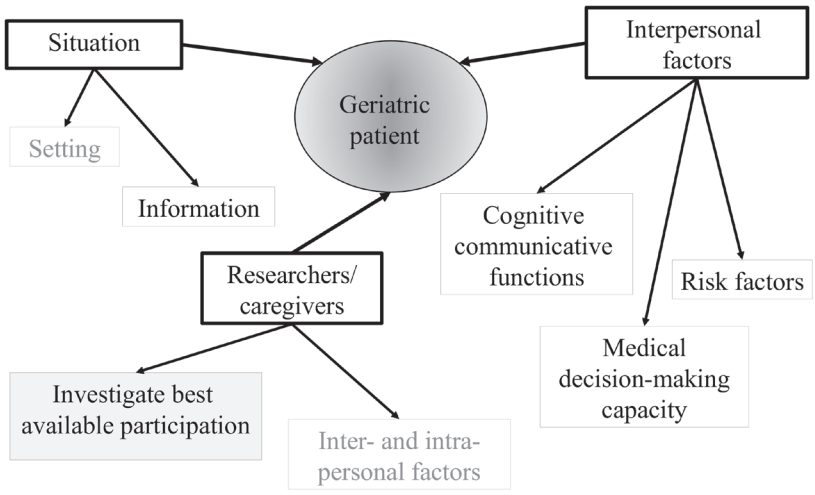


Figure 4. Factors influencing a geriatric patient's possibilities to participate in medical decision-making processes. Words in black indicate areas investigated within the doctoral project. Other aspects, covered in the background, are included to give a wider perspective. The responsibility of staff to examine and promote best available participation is high-lighted in *Discussion.*

1.4.1 Support the patient

Communicative memory aids are considered to support both cognitive and communicative skills, by helping the patient find words, recall memories and stay on topic. The aids can consist of drawings, photographs, individual words and/or phrases. The aids aim to take advantage of the often preserved automatic speech, as well as the desire to communicate.[126] One example of a method using a cognitive communicative based approached with pictures and/or words is Talking mats (TM).

TM is a method which facilitates for an individual to organize thoughts and express opinions. Its foundation is a textured mat showing a scale illustrated with simple images that express a person's opinion (ranging for example from "I like it" to "I do not like it"). The mat is placed before the person in need of support, and questions are posed, one at a time, each one illustrated with one picture, and often a keyword below the picture. The respondent gives his or her answer by placing the picture below the scale step they think is appropriate, along with any verbal response if possible. This visualizes the respondent's answers and put the answers in relation to each other, helping to compare them. While the method aims to support the patient, the caregiver is the one who needs to learn the method, and also prepare each topic and pictures.[127]

Previous studies have shown that when individuals with dementia use TM it increases communication efficiency by enhancing their understanding, their engagement in conversation and their ability to keep on track. Crucially, they were understood to a greater extent than

when they participated in a structured or non-structured interview.[127] Both patients and their informal caregivers reported positive outcomes in terms of clarifying thoughts and feeling more listened to. In contrast to many other suggested models and methods,[126,128] TM has been evaluated using measures of communication outcomes.[127]

1.4.2 Change factors in the situation

One way to facilitate understanding is to increase readability of participant information, using simpler language and/or complementary written information with pictures.[30,129] Linguistic elements that make a text more or less difficult to understand are well known. Among them are mean sentence length, mean word length, number of difficult words, how many subordinate clauses there are on average per sentence, mean parse tree height and idea density.[130] The readability of written information to patients can be improved by choosing the linguistic structure carefully. However, when it comes to informed consent to hypothetical trials, the readability may not be the most important obstacle to overcome.[131]

Information to participants in medical research contains medical and technical terms that are rarely used in everyday speech, but which cannot be excluded without loss of vital information. The level of difficulty in participant information often surpasses the level that readers are assumed to understand.[132] A study comparing patients' understanding of a standard information consent document versus an improved consent document (improved by altering structure and readability) found no objective improvement in understanding.[131] Trying to increase readability does not necessarily improve participants' ability to give truly informed consents.[131,133-136]

1.5 COMPARING MEDICAL DECISION-MAKING CAPACITY, PATIENT PARTICIPATION AND HEALTH LITERACY – A SUMMARY

Communication is a necessary topic when discussing geriatric patients' medical decision-making capacity, participation and health literacy alike. Sufficient hearing, vision and a shared language are basic requirements. *Receptive linguistic skills* are fundamental to participation in medical decision-making process. Understanding is the first requirement before it is possible to process and act on information. Understanding is highlighted in MDC, patient participation and health literacy alike. *Cognitive communication functions* are needed to process information and reach a decision. MDC, patient participation and health literacy emphasize the need to ponder information and apply it to one's own situation. *Expressive language skills* are important in MDC, patient participation and health literacy alike, in order to communicate a choice. However, while MDC focuses on the ability to provide a clear and consistent choice, patient participation and health literacy also concern the patient's ability to provide information to the caregiver, regarding for example symptoms or preferences. A compilation of three communicative aspects of decision-making in medical contexts

is found in Figure 5. The overall aim of this thesis is to investigate medical decision-making capacity in geriatric patients with and without dementia using communication-based approaches to assessment and facilitation.

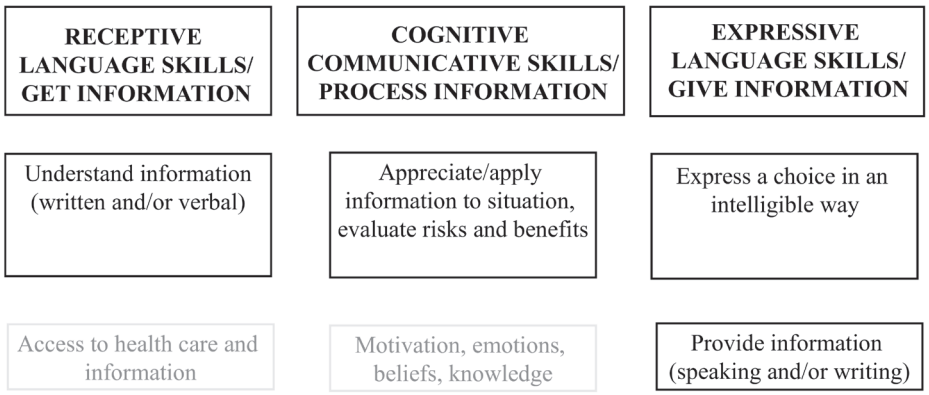


Figure 5. Three aspects of communication in medical decision-making processes – found in the upper boxes – derived from definitions of medical decision-making capacity, health literacy and patient participation. The boxes in the middle row are included in all three definitions, while the boxes in the bottom row contain aspects only included in definitions of health literacy and patient participation. The boxes in black are addressed within the studies included in this thesis, while boxes in grey are not.

2 METHODOLOGICAL CONSIDERATIONS

2.1 PARTICIPANTS

The projects included geriatric patients with and without dementia, in-patients and out-patients, as well as a healthy control group. Table 1 contains an overview of the participants in each study, including number of subjects, inclusion criteria, participants' mean age, mean score on cognitive screening tests and mean years of formal education.

Study I concerned geriatric in-patients *with* cognitive impairment, while study IV included geriatric in-patients *without* known cognitive impairment. The two studies that included out-patients also had participants both with and without dementia. Only participants with Alzheimer's disease (AD) were recruited for study II, while participants with AD, Mild cognitive impairment (MCI) and healthy controls were included in study III.

Clinical investigation of patients with suspected AD at the memory clinic followed criteria in ICD-10 and internationally established diagnostic standards.[137] AD is characterized by an insidious onset and progressing impairment of cognitive functions. Deficits in memory typically appear first and are most readily noted. Other effects that appear early are language impairment, worsened perception, and difficulties with abstract thinking.[7,8] For the studies reported here, a multi-disciplinary team performed a clinical examination, routine laboratory status, status regarding daily life and cognitive functions and a magnetic resonance imaging of brain. Cerebrospinal fluid biomarkers were analyzed unless contraindications were present. In the recruitment procedure for study II and III, participants with cognitive impairment were required to score at least 20 points on Mini-mental state examination (MMSE), a screening test of overall cognitive function.[138] It was postulated that patients who scored lower would not be able to participate in the test situation. Diagnosis criteria for MCI include subjective complaints of declines in cognitive functions which could be verified with objective tests. Other inclusion criteria were adequate global cognitive function and preserved activities of daily life.[9]

A difference between the studies' focuses was whether the primary aim was to investigate a specific method, or to describe a specific aspect of reality at hospital wards at a given time. Study I and IV aimed to reflect actual status at wards, and therefore had more generous inclusion criteria than study II and III. For study II and III, Swedish was required as the participant's native language, or one of them if bilingual. For study I and IV the inclusion criterion was instead set to ability to communicate in Swedish without an interpreter. A similar distinction between the studies regarded depression. Depression as measured by a score on Cornell's depression scale ≥ 9[138B] was an exclusion criterion in study II and III, but not in study I and IV. Study I and IV overall had similar inclusion/exclusion criteria, with the exception of documented cognitive impairment. A patient with severe aphasia was excluded

mainly because it was impossible to gain informed consent, but the patient would have been unable to participate in the test situation. The use of different samples in the different studies warrants caution when integrating and interpreting the results.

The inclusion procedure varied between studies. For study I and IV, in-patients were asked to participate in the respective studies, whereas for study II and III, a letter of invitation was sent to patients' homes. Compilations from weekly diagnostic rounds at a university hospital's memory clinic were used to identify possible participants. Healthy controls for study III were recruited as part of a master's thesis.[139] All participants were recruited within the wider geographic region of Stockholm.

The mean age of groups diagnosed with AD was 73.6±8.2 in study II, and even lower, 67.3±7.2, in study III. This participant age span, relatively low among publications dealing with AD, might reflect today's clinical interest in diagnosing AD as early as possible. The in-patients with dementia or other cognitive impairment included in study I had similar mean ages in Talking mats group (TMG) and Control group (CG). The highest mean age was found in the group of in-patients without known cognitive impairment who participated in study IV: 82.0±7.3 years.

A comparison of the participants' actual screened overall cognitive function showed that participants in study IV, for which known cognitive impairment or acute confusion was an explicit exclusion criterion, had mean scores as low as those of the participants with documented cognitive impairment in the other studies. As a group, these in-patients with somatic illnesses showed a screened overall cognition at dementia level.

Nota bene that two different tests were used to screen overall cognitive function: MMSE[138] and Montreal cognitive assessment (MOCA).[140] MMSE has an original passing cut-off score of 24/30, but it has been argued that, especially for individuals with longer formal education, this may be too low to detect subtle cognitive impairment.[141,142] MOCA on the other hand has a higher original passing cut-off score, 26/30. Even though a correction for short formal education is made when scoring, a meta-analysis argued that the cut-off score should be even lower.[143] MOCA was preferred to MMSE in study III and IV due to its ability to detect subtle changes in cognitive impairment.[144,145]

Table 1. An overview of participant data.

	Study I	**Study II**	**Study III**	**Study IV**
Number of participants	TMG, n = 12 CG, n = 8	n = 24	AD, n = 28 MCI, n = 14 HCG, n = 21	n = 44
Inclusion criteria				
Language	Communicate in Swedish without interpreter	Swedish as (one of) native language(s)		Communicate in Swedish without interpreter
Hearing and vision	No severe hearing or vision impairment that was not corrected by aids			
Depression	*Not a criterion*	No depression		*Not a criterion*
Dyslexia		No self-reported dyslexia		
Cognitive status	Documented cognitive impairment	Diagnosed with AD within last 12 months (MMSE ≥ 20 p)	Diagnosed with AD or MCI within last 12 months (MMSE ≥ 20 p)	No documented cognitive impairment
Additional criteria	Ability to use Talking mats	*No additional criteria*	HCG: No diagnosis that affects language/ cognitive ability (self-reported)	No severe general condition No acute confusion
Age in years	TMG: M = 76.8, CG: M = 70.8	M = 73.6	AD: M = 67.3 MCI: M = 65.9 HCG: M = 63.8	M = 82.0
Screening of overall cognitive function (score)	*MMSE* TMG: M = 21.4 CG: M = 20.3	*MOCA* M = 24.7	*MOCA* AD: M = 19.5 MCI: M = 24.3 HCG: M = 27.0	*MOCA* M = 21.2
Formal education (years)	*Not documented*	M = 10.3	AD: M = 10.9 MCI: M = 12.5 HCG: M = 12.2	M = 10.2

AD = Alzheimer's disease
CG = Control group (patients)
HCG = Healthy control group
MCI = Mild cognitive impairment
MMSE = Mini-mental state examination[156]
MOCA = Montreal cognitive assessment[157]
TMG = Talking mats group

Table 2. Overview of study design

	Study I	**Study II**	**Study III**	**Study IV**
Aim	Facilitation: Evaluating Talking mats in discharge planning meetings	Facilitation: Evaluating Adapted vignettes for patients with Alzheimer's disease	Assessment: Developing and validating KIMB, a test to detect impaired MDC	Assessment: Investigating prevalence of impaired MDC measured with KIMB among in-patients
Design	Prospective, randomized controlled trial	Prospective, randomized controlled trial	Prospective, cross-sectional design	Prospective, cross-sectional design
Settings	Geriatric ward	Out-patients	Out-patients, healthy controls	Geriatric wards
Data collection period	June 2013 – June 2014	Aug 2014 – Sept 2015	Sept 2015 – Sept 2017	Jan – March 2018
Data analysis	Evaluation by VAS (patient, family, nurse, social care worker)	Evaluation by LIMD	Evaluation of validity	Evaluation by KIMB and investigating risk factors
Ethical approval reference number	2013/167-31/1	2008/1764-32	2008/1276-31/2 and 2009/1764-32	2017/1917-31/1

KIMB = Clinical instrument of medical decision-making capacity
LIMD = Swedish linguistic instrument for medical decision-making
MDC = Medical decision-making capacity
VAS = Visual analogue scale (100 mm)

2.2 SETTING AND DESIGN

In order to obtain a representative sample from the population, the studies in this thesis shared a prospective, consecutive study design, with predefined study protocols including inclusion and exclusion criteria. Table 2 gives an overview of the studies' designs, including aims, settings, data collection periods, data analysis and ethical approval reference numbers from the regional ethics committee in Stockholm. In study I, the setting was a geriatric ward where patients with suspected dementia were examined and diagnosed by a multi-professional team, whereas in study IV the setting was three geriatric wards with focus on stroke/neurological diseases and multi-morbidity/internal medicine.

A holistic approach was sought by including both studies that focused on facilitation and on assessment in medical decision-making processes. Within this framework, it was possible to integrate and interpret results from different settings, that involved different materials and participants. Study I and II evaluated one intervention procedure each: Talking mats and Adapted vignettes. In study III, the focus was on the construction and validation of a text-based test to detect impaired medical decision-making capacity (MDC). Study IV investigated prevalence of impaired medical decision-making capacity among geriatric in-patients without known cognitive impairment.

One endeavor in all studies was that meetings with participants should take place in an as calm an environment as possible. For participants recruited outside the hospital, this was a minor problem. A quiet room was readily available regardless of whether the participant was met at the clinic or in his/her own home. On the other hand, in-patients commonly shared a room with at least one other patient. While the wards had small rooms used, for example, for discharge meetings and team rounds, some background noise was typically noted.

In study II each participant read the vignettes in a different and unique order, so as to eliminate any test order effect. Conversely, test order was the same for all participants in study III and IV to ensure that any test order bias would be constant.

2.3 MATERIAL

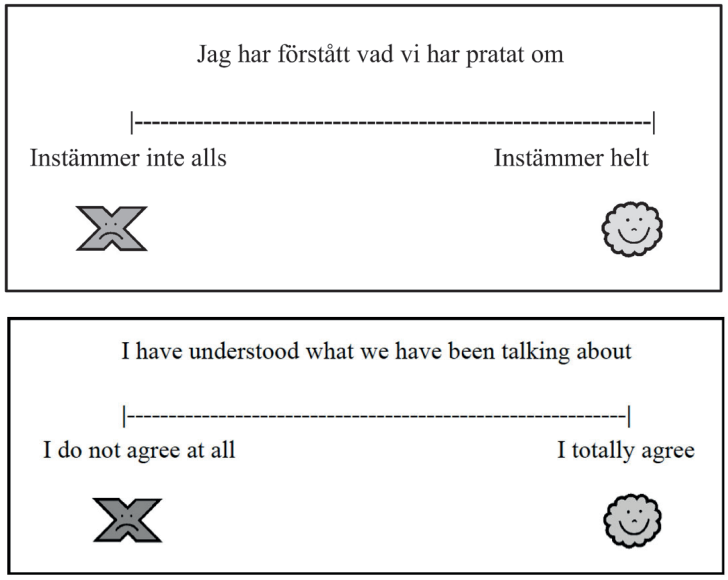
2.3.1 Talking mats

Talking mats (TM) was used to help patients prepare prior to discharge meetings in study I. The subject addressed in the TM session was labeled "you", to focus on the patient's own ability to perform activities of daily living and need of assistance and care after discharge. Questions appropriate to include in the TM session were those likely to be discussed during the discharge meeting. The questions were identified by participating in discharge meetings at the ward. Suggested questions were discussed with an experienced nurse at the ward. In

total, 26 pictures were prepared, but each participant chose which pictures/questions felt relevant to him/her. In study I, Figure 1 shows examples of pictures used.

Communication in each discharge meeting was evaluated afterwards by patients, a family member, nurses and social care workers on visual analogue scales (VAS). All persons attending the discharge meetings were informed about the study prior to the meeting, and the evaluation sheets were presented. Sheets for each group (patients, family members, nurses, social care workers) were left in the room, together with an instruction that if anyone wanted to participate, they could fill in the VAS immediately after the meeting.

The statements on VAS aimed to address the patient's communication, and therefore differed in pronoun, for example: *I have understood what we have been talking about* as compared to *I perceive that the patient understood what we have been talking about*. Each statement on the patient's paper with VAS was illustrated using the same scale picture as in the TM session. Figure 6 shows an example of a statement used for evaluation. In this study, there was no objective analysis of actual communication; rather, the focus was the participants' experiences of the communication.



Source: Personal collection

Figure 6. First statement on the visual analogue scale to evaluate how communication had been functioning during the discharge planning meeting in study I, with an English translation below.

2.3.2 Swedish linguistic instrument for medical decision-making

The original version of the test Swedish linguistic instrument for medical decision-making (LIMD) included three vignettes: Kidney disease, Hypertension and Skin disease. The hypothetical clinical trials presented in the vignettes regarded evaluation of new medical treatments. The trials differed with regard to potential risks and benefits for participating subjects. The texts with information to possible participants also differed in terms of how serious the imagined underlying disease was. The Kidney disease vignette described a hypothetical trial with low personal risk and high potential benefit in 249 words. The Hypertension vignette described a trial with high personal risk and low potential benefit in 525 words. In the Skin disease vignette, an intermediate personal risk was accompanied by an intermediate potential benefit.

When using LIMD to assess an individual's understanding, the assessor read aloud to the participant, one vignette at a time, but the participant could read along in his/her own copy of the vignette. After each vignette, a standardized interview with nine questions followed. The standardized interview assessed MDC according to three aspects defined in LIMD: comprehension, evaluation and intelligibility of choice. The interviews were audio recorded, transcribed and scored according to LIMD's protocol based on linguistic features.[24] Figure 7 shows excerpts from the questions used in the standardized interview. The validation study of LIMD included participants with early stage AD, MCI and healthy controls. Intra-rater reliability was high (r = .94), as was the inter-rater reliability (r = .89).[24] For study II, a new intra-rater reliability was calculated by re-scoring 20 interviews (r = .89). The 20 interviews were selected to represent a range of scores, from minimum to maximum.

2.3.3 Adapted vignettes

A comprehensive linguistic analysis based on responses made by persons with AD in the LIMD validation-study was performed. The aim was to identify which linguistic features were difficult for patients with AD to comprehend, and after identifying these features, make the information easier to understand by altering these constructions. The six identified difficult features were: 1) long sentences, 2) subordinate clauses, 3) compound word and technical terms, 4) words with negative association, 5) passive verbs and 6) comparatives. The project resulted in two new, linguistically adapted vignettes, which were hypothesized to facilitate understanding for patients with AD.[146] The material used in study II was two of the original vignettes in LIMD (Kidney disease and Hypertension), and their two corresponding Adapted vignettes. Figure 8 shows a flow chart of the process to create the Adapted vignettes. In study II, each participant read the original Hypertension and Kidney disease vignettes, as well as their two corresponding Adapted vignettes, to compare if Adapted vignettes facilitated MDC. The interviews were audio recorded and afterwards anonymized and transcribed verbatim prior to scoring.

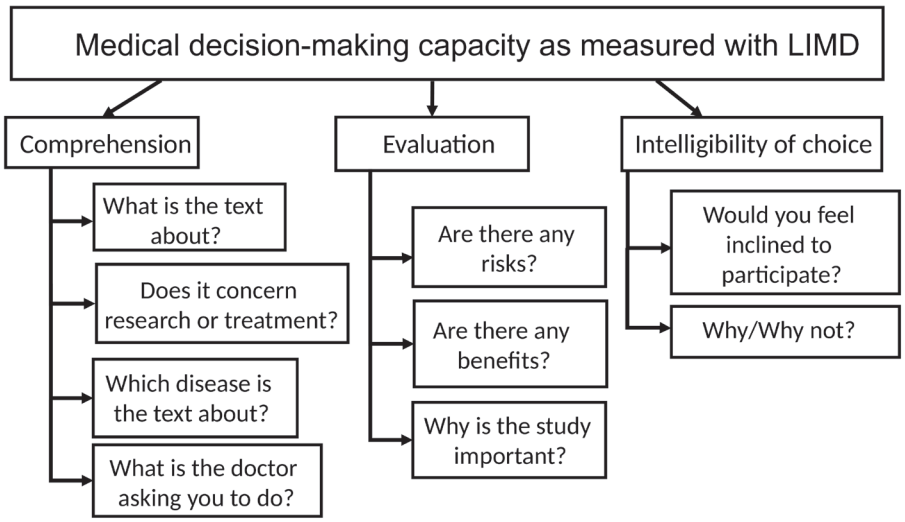
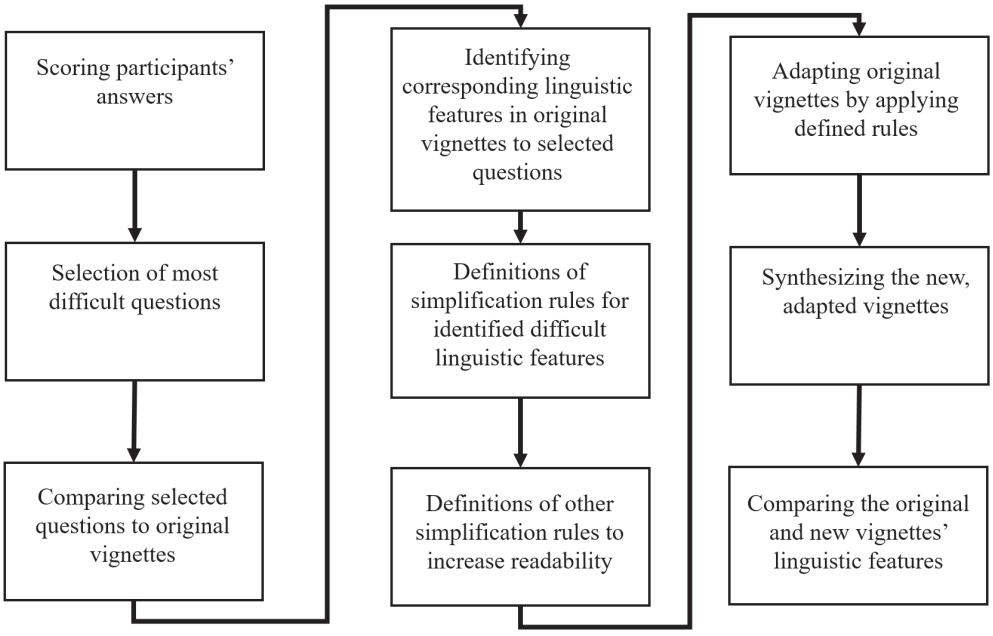


Figure 7. Excerpts from the questions included in the standardized interview concerning Swedish linguistic instrument for medical decision-making (LIMD), grouped by which aspect of medical decision-making capacity they aimed to assess: comprehension, evaluation or intelligibility of choice.



Source: Adapted from Daniela Gabrielsson, 2013,[146] with permission.

Figure 8. The process of linguistically adapting the original Hypertension and Kidney disease vignettes in order to create Adapted vignettes, which were hypothesized to be easier for persons with AD to comprehend.

2.3.4 Sentence structure, vocabulary load, idea density, and human and personal interest

Sentence structure, vocabulary load, idea density, and human and personal interest (SVIT) is a computer-based method to assess the readability of a text using surface features and deep linguistic features.[130] The SVIT method was used to compare original and adapted vignettes, and to describe linguistic features of KIMB. A text's surface features lie in its actual form, such as number of words per sentence. The deeper linguistic features include vocabulary, sentence structure and idea density. Vocabulary load is calculated by counting words not included in SweVoc, which is a Swedish vocabulary list consisting of the 7100 most commonly used lemma words.[149] The syntactic complexity in sentence structure is analyzed using parse tree derivation. Each sentence is organized and labelled based on its syntactic structure, which is distinguished from the sentence's meaning. This organization results in hierarchical nodes. Counting these nodes gives a measure of syntactical complexity; the higher the number of nodes, the more syntactically complex is the sentence. Figure 9 shows an example of a parse tree. Idea density is calculated as the number of nouns, prepositions and participles divided by the number of verbs, pronouns and adverbs.[130]

2.3.5 Clinical instrument of medical decision-making capacity

The Clinical instrument of medical decision-making capacity (KIMB) was constructed with the aim to be fast and easy to use in medical contexts and can typically be completed within ten minutes. KIMB was based on the vignette method and a hypothetical clinical trial, thus measuring the capacity to give informed consent, based on a hypothetical situation.

The following guiding principles were applied in the construction of KIMB:

- The vignette should concern MDC for informed consent.
- The content should cover comprehension, evaluation and decision.
- Deep and surface language characteristics of the test should be similar to those of the test *Diagnostic material for analysis of reading and writing skills (DLS) Reading speed*, which assesses reading speed and reading comprehension. The test should also have similar construction with embedded brackets containing three word to chose from as DLS Reading speed.[147] The reason was twofold: 1) DLS Reading speed showed strongest correlation to MDC as measured with LIMD in a previous study,[32] and 2) previous studies had shown that patients with early stage of AD could read the text.[32,133] Surface and deep language structure were analyzed using SVIT.[130] A compilation of the SVIT analysis is presented in study III, Table 1.
- Tasks should engage all five reading levels as described by Mullis et al.[148]:
    1. Recognize words and phrases
    2. Understand sentences and simple paragraphs
    3. Retrieve explicitly stated information
    4. Make straightforward inferences
    5. Comprehend the overall message

KIMB emphasizes the role of reading skills in MDC, since KIMB contains two written tasks, but no interview. The participant's task was first to identify target words within the vignette, then complete a questionnaire. Throughout the vignette were embedded comprehension tasks where the right word out of three in a bracket should be chosen while reading the text. The questionnaire consisted of multiple-choice questions based on the information from the vignette. The questions addressed comprehension, evaluation and choice.

While KIMB shared LIMD's focus on linguistic features in MDC, the test had innovative features. The vignette was written in third person instead of first person pronoun. By naming a fictitious character, the test constructors sought to minimize the risk of confusing persons with dementia. Furthermore, the idea of using a vignette to assess understanding while reading, and subsequently using the same vignette to assess all three aspects of MDC was a new approach. Figure 10 shows a compilation of tasks in KIMB, and Figure 11 three examples of tasks from KIMB.

S = sentence (root node)
N = noun (leaf node)
NP = noun phrase (branch node)
V = verb (leaf node)
VP = verb phrase (branch node)
D = determiner (leaf node)

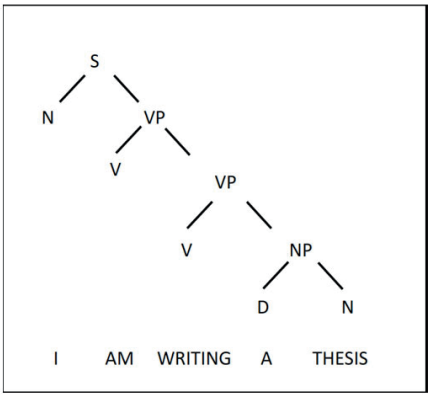


Figure 9. An example of a parse tree with five node levels.

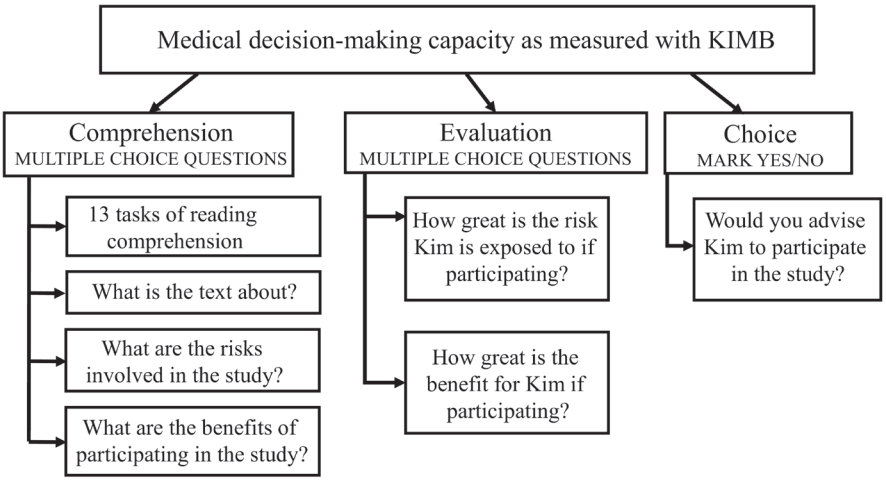


Figure 10. A compilation of tasks in Clinical instrument of medical decision-making capacity (KIMB), grouped by which aspect they aimed to assess: comprehension, evaluation and choice.

1. Dolorsjukan kan [smitta forcera drabba] både män och kvinnor och debuterar vanligtvis runt 50-60 års ålder.

2. Vad handlar texten om?

   ☐ Erbjudande om en gratis och välbeprövad medicin

   ☐ Undersökning av effekten hos ett nytt läkemedel

   ☐ Behandling för att minska kramper

3. Hur stor nytta har Kim av att delta i studien?

   ☐ Mycket liten ☐ Liten ☐ Stor ☐ Mycket stor

---

1. The Dolor disease can [infect crash strike] men and women alike and usually has an onset around the age of 50-60 years.

2. What is the text about?

   ☐ Offer of a free and proven medication

   ☐ Investigating the effect of a new drug

   ☐ Treatment to reduce seizures

3. How much benefit does Kim have by participating in the study?

   ☐ Very small ☐ Small ☐ Large ☐ Very large

Source: Adapted from Clinical instrument of medical decision-making capacity, personal collection

Figure 11. Examples from Clinical instrument of medical decision-making capacity, showing three types of tasks set for participants: 1) selecting the right word, 2) demonstrating understanding, and 3) evaluating the information. The examples in Swedish are followed by English translations.

The following steps were applied before the final version of KIMB was decided on and the validity study was carried out:

1. A first version was constructed.
2. Colleagues voluntarily tried KIMB and gave feedback.
3. A group of voluntary speech and language pathology students tried KIMB.
4. KIMB was adjusted, mainly with respect to phrasing in the questionnaire, in order to avoid ambigouness.
5. Each task in the first part with embedded words was checked for most common word order frequency in a corpus analysis.[A] Of the three word choices, the correct word was always the one the corpus showed most commonly followed the word before the brackets. In some cases, none of the words in brackets were found to follow the word before the brackets. The incorrect words were never allowed to be more common after the word before the brackets than the correct word – thus avoiding tricky questions.
6. Groups of healthy controls and of patients were assessed with KIMB and their results compared. Healthy controls were recruited among staff at hospital and extended networks of older relatives. The patients were seeking care at a speech and language pathology clinic.

[A] The corpus analysis was performed with "Korp" www.spraakbanken.gu.se, with only medical texts chosen as reference.

In the validation study of KIMB, five other tests were chosen as reference points: *DLS Reading speed*,[147] *Inference* and *Repetition of long sentences* from the test battery test battery of high-level language functions (BeSS),[151] *Rey auditory verbal learning test* (RAVLT),[152] *Montreal cognitive assessment battery* (MOCA)[140] and *Word sequence production*.[154] The tests were chosen since they had previously shown strong correlations to MDC as measured by LIMD. The correlations were deemed strong enough to warrant not using LIMD. To exclude LIMD was desirable from an ethical point of view: LIMD assessments would have been more laborious and time-consuming for the participants. Not using LIMD held advantages for participants that were considered to outweigh the disadvantages of not being able to correlate KIMB directly to another test of MDC.

The test orders in study III and IV were determined by the same principles:

- KIMB was presented first, in order to avoid any effects of other tests.
- The easiest task was presented last.
- DLS Reading speed should not follow immediately after KIMB.

Apart from LIMD, no tests required a specific analysis but answers were simply marked right or wrong, or in the case of timed tasks such as Word sequence forward, time to completion. No inter- or intra-rater reliability tests were therefore performed. Detailed specifications and descriptions of the tests included is found in study II-IV.

2.4 ETHICAL CONSIDERATIONS

Persons with dementia or other documented cognitive impairment are a vulnerable population to include as participants in clinical research. Their cognitive impairment and high likelihood of struggling with understanding information and giving truly informed consent warrant extra precautions. The two main reasons for including participants with different degrees of cognitive impairment in projects in this thesis were: the research questions could not be answered by using other participants, and the research results would benefit the patient group itself. One important risk to address is that patients may feel dependent on health care staff while being at a ward. The person who recruited and tested participants in study I and IV was not involved in any of the patients' ordinary care at the ward. This strategy was an attempt to minimize the risk of patients feeling in any way pressured to participate in the study. During sessions, it was repeatedly emphasized that participation was voluntary and that the patient could withdraw from the study without needing to give any explanation.

The information given to participants prior to inclusion in any of studies I-III was presented both in written form and verbally. All participants had the possibility to ask for clarifications and to pose any questions to the researcher. In order to facilitate understanding, an extra sheet was added to the standard written participant information with pictures and keywords addressing vital parts of the information for inclusion to study IV.

2.5 DATA ANALYSIS

All statistical analyses were quantitative and preceded by checking assumptions for each respective test. Study I and II mainly used parametric tests, while in study III and IV mainly non-parametrical tests were utilized. All calculations were made in SPSS (version 22.0.0.1 or 24.0.0.0).

In study I, differences between the four groups (patient, next of kin, nurse, social care worker) and the three statements were analyzed using a *two-way independent ANOVA*, since beside differences between groups, also any interaction effect was deemed of value to investigate. The dependent variable (score on VAS) was continuous, while the two independent variables (group and statement) were categorical. All observations were mutually independent. There were no significant outliers as evaluated by z-scores (±2.0), and the data were approximately normally distributed for each combination of the two independent variables. Not all combinations of the independent variables showed a homogeneity of variances (as checked with *Levene's test for homogeneity*), but the violations were deemed non-significant.

Differences in the total score on VAS (Statement 1 + 2 + 3) between discharge meetings that used Talking mats and those that did not were investigated with an *independent samples t-test*. The dependent variable was continuous, the independent variables were the two categorical groups. There was an independence of observation, and no significant outliers as evaluated by z-scores. The dependent variable was approximately normally distributed for both groups, checked with *Shapiro-Wilk test* ($\rho>0.0$). Homogeneity of variance was not calculated since groups were approximately equally large. The effect size was calculated using *Hedge's g*, a measure based on standard deviations. Hedge's g can preferably be used for small samples since Cohen's *d* overestimates the variance explained in the population.

In study II, any differences on LIMD score in relation to the two within factors – readability (Original or Adapted vignettes) and type of hypothetical trial (Hypertension or Kidney disease) – were analyzed using a *two-way repeated measures ANOVA*. Beside differences between groups, any interaction effect was also of interest to investigate. The dependent variable (score on LIMD) was continuous, while the two independent variables (readability and trial) were categorical. The observations were related. There were no significant outliers as evaluated by z-scores, and approximately normally distributed data for each combination of the two independent variables. Since both within factors only had two levels, the assumption of sphericity was met. The effect size was calculated with *eta-squared*, which is commonly used in ANOVA. The interpretation of eta-squared

is straightforward; it is a measure of the proportion in one variable that can be attributed to another. However, although eta-squared gives a correct measure of proportion within the sample, it overestimates the variance explained in the population, especially in small samples, where the use of omega-squared could be considered instead.

Pearson product-moment correlation was used to calculate correlations between scores on LIMD and on each of the other included tests. The assumptions of continuous variables, linear relationships, no significant outliers and approximately normally distributed variables were met.

In study III, several of the variables presented either with outliers and/or were not normally distributed within each group, and the non-parametric *Kruskal-Wallis H test* was used to investigate any significant differences between the three groups of participants (AD, MCI, HCG). The assumptions of Kruskal- Wallis H test were met: the dependent variable was continuous (score on KIMB), the independent variable consisted of three categorical groups, there was independence of observations and the distribution of scores for each group had approximately the same shape. *Mann-Whitney U test* was used for pairwise comparisons (its assumptions equaling those for Kruskal-Wallis H test besides only two categorical groups being allowed). Statistically significant results were defined as $\rho<.05$ for Kruskal-Wallis H test, and with Bonferroni correction for the multiple post-hoc comparisons, $\rho<.16$. *Partial eta-squared* was calculated as measure of effect size. Whereas eta-squared is the proportion of total variance explained by another variable, partial eta-squared is the proportion of variance that is *not* explained by other variables. This more conservative measure was preferred due to use of non-parametric calculations.

The non-parametric test *Kendall's tau–b* was used to calculate correlations between scores on KIMB and on each of the other tests. The two assumptions of variables being continuous and having a monotonic relationship were fulfilled. Kendall's tau–b was preferred to Spearman's rank correlation coefficient due to the relatively small sample size and relatively high number of tied ranks.

A measure of the overall diagnostic accuracy of KIMB was calculated using ROC curve and Area under the curve. Cross-tabulations based on values from ROC curve table were used to determine cut-off value for KIMB, and for calculating sensitivity and specificity.

In study IV, a *one sample t-test* was used to investigate if the sample's score differed from the KIMB cut-off value. The assumptions of continuous variable, independence of observations, no significant outliers and approximately normally distributed data were met.

Data for correlations fulfilled criteria for *Pearson's product moment correlation*, with continuous data, a linear relationship, no significant outliers, and approximately normally distributed data as controlled for with Shapiro-Wilk test of normality.

This study had an explorative approach to risk factors, and did not investigate causational relations. Each risk factor was evaluated separately, and no adjustment was made for multiple comparisons. Even though the factors were chosen based on previous research, this analysis approach increased the possibility of false positive findings (type I errors). Therefore a more stringent significance value was set for the correlation analyses: $\rho \leq .01$.

The non-parametric *Mann Whitney U* test was used to investigate any differences on KIMB score between those subjects who had Swedish as a first language, and those (only five) who had learned Swedish as adults, due to large disparity in group sizes.

3 INTEGRATED RESULTS

3.1 MEDICAL DECISION-MAKING CAPACITY IN GERIATRIC PATIENTS

3.1.1 Participants with Alzheimer's disease and Mild cognitive impairment

Participants with Alzheimer's disease (AD) showed impaired medical decision-making capacity (MDC) as assessed by Swedish linguistic instrument for medical decision-making (LIMD) and Clinical instrument of medical decision-making capacity (KIMB). Median score on KIMB for the group with AD was 13(1-16). Patients with Mild cognitive impairment (MCI) showed a marginally higher median score on KIMB, 14(11-19) compared to the AD group, but lower compared to the healthy control group, 15(12-19). The differences in score between the three groups were statistically significant. Pairwise comparisons showed that KIMB score in the group with AD was significantly lower than that in the group with MCI and the healthy control group (HCG), while no significant difference was found between HCG and MCI.

There was no significant difference in MDC as measured by LIMD among patients with AD depending on whether original or adapted vignettes were used. A small significant difference was found to depend on trial. Patients showed marginally higher scores on LIMD when Kidney disease vignettes were used, as compared to when Hypertension vignettes were used.

One way to illustrate how impairment in MDC manifested in patients with AD, is to go back to the scoring instructions for LIMD. The low mean score means that the participants, on average, did not even score one point on each of the three assessed aspects of MDC: comprehension, evaluation, intelligibility of choice. The scoring protocol stated that one point should be given for comprehension if *Answers showed some uncertainty regarding if information had been correctly understood*, specified with the following examples:

- Showed some difficulties in perceiving and understanding the content of the vignette.
- Explained the content only partially.
- Consisted to a large extent of reading parts of the vignette aloud.
- Consisted only occassionally of own wordings.
- Were incomplete.
- Consisted, to some extent, of misunderstanding, erroneuos answers or *do not know* – answers.

Another way to illustrate MDC among the participants with AD is by examples from the transcribed interviews. The examples in Figure 12-15 highlight:

- The specific problem of distinguishing a hypothetical vignette from the patient's own situation.
- The difference between agreeing to a standard treatment procedure and participating in a clinical research was not self-evident.
- Making these kinds of medical decisions was hard.
- Participants occasionally showed preserved capacity to value information.

The examples are taken from interviews with different participants. Each example contains excerpts from the Swedish transcriptions together with an English translation.

A	**A**
Testledare: hade du varit beredd att delta? Deltagare: ja jag vet faktiskt om ja säger osäker i och med att ja har så många saker som inte stämmer in riktigt ( )	Assessor: would you have been willing to participate? Participant: well I know actually I would say I'm not sure because I have a lot of things that don't quite fit ( )

Figure 12. Transcription from an interview based on one of the hypothetical Hypertension vignettes as part of assessment of medical decision-making capacity by Swedish linguistic instrument for medical decision-making. The participant showed by the response that he/she had not grasped the idea that the vignette concerned a fictitious situation, since the explanation referred to his/her own conditions.

B	**B**
Testledare: handlar det om forskning eller om behandling? Deltagare: ja det tror ja definitivt	Assessor: does it concern research or treatment? Participant: yes I'm sure of it

Figure 13. Transcription from an interview based on one of the hypothetical Kidney disease vignettes as part of assessment of medical decision-making capacity by Swedish linguistic instrument for medical decision-making. The participant showed by the response that he/she had difficulty grasping the difference between routine, standard treatment procedures and drug trials in medical research.

C	**C**
Testledare: hade du varit beredd att delta? Deltagare: (4s) förmodligen men ja e inte helt säker faktiskt	Assessor: would you have been willing to participate? Participant: (4s) probably but actually I'm not that sure

Figure 14. Transcription from an interview based on one of the hypothetical Kidney disease vignettes as part of assessment of medical decision-making capacity by Swedish linguistic instrument for medical decision-making. The participant highlighted by his/her response that medical decisions, like deciding whether to participate in a medical trial or not, can be a complex process.

D	D
Testledare: hade du varit beredd att delta? Deltagare: nej Testledare: varför hade du inte velat delta? Deltagare: nej de ja skulle inte utsätta mej för dom här grejorna nej de e en inbyggd självbevarelsedrift som mänskan normalt har eller en del kanske inte har den men därvidlag har jag en skvätt av den	Assessor: would you have been willing to participate? Participant: no Assessor: why would you have declined to participate? Participant: no well I wouldn't expose myself to that stuff no it's a built-in survival instinct people normally have or maybe some don't have it but in that respect I have a bit

Figure 15. Transcription from an interview based on one of the hypothetical Hypertension vignettes as part assessment of medical decision-making capacity by of in Swedish linguistic instrument for medical decision-making. The vignette described a hypothetical drug trial with very high risks and very low benefits for participants. The participant showed by the response that in spite of the cognitive impairment that follows with his/her diagnosis of AD, he/she understood the information in the vignette and provided a valid reasoning as why to decline participation.

3.1.2 Clinical instrument of medical decision-making capacity

An innovative approach in the validation study of KIMB was to calculate a cut-off score as when to pass or fail KIMB. The highest values for sensitivity (75%) and specificity (91%) were obtained when ≥14 points (of 19) was set as cut-off score. The high specificity level indicated that most healthy adults pass the test, while the somewhat lower sensitivity level indicated that also some individuals with presumed cognitive impairment will pass. The overall diagnostic accuracy of KIMB was derived from a Receiver operating characteristic (ROC) curve. The ROC curve plots the diagnostic properties of a test, using different cut-off values. The y-axis shows the true positive rate (sensitivity), and the x-axis shows false positive rate, calculated as (1 – specificity). The ROC curve and its adherent coordinates of the curve are used to find the best cut-off value of a test, which is when both sensitivity and specificity level are highest. The Area under the curve is used as an overall measure of a tests overall diagnostic validity. The Area under the curve was 0.87 which indicated that KIMB was a good test.[150] These calculations were made based on the AD and HC groups only. With a cut-off value it was possible to calculate prevalence number of suspected impaired MDC. Figure 16 shows the ROC curve, including Area under the curve and a null-hypothesis line.

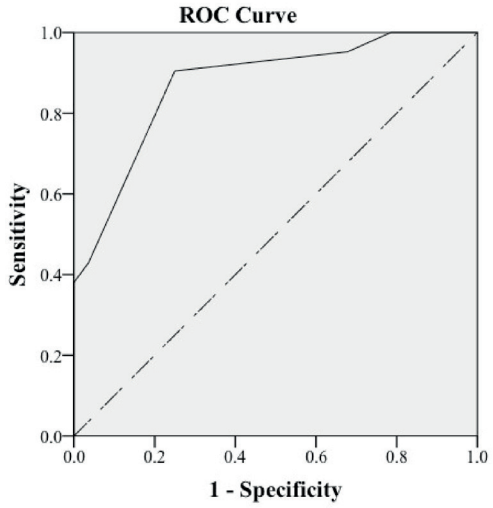


Figure 16. ROC curve and Area under the curve based on score on KIMB. Participants with Alzheimer's disease was used as reality check for impaired medical decision-making capacity, and healthy controls as reality check for preserved medical decision-making capacity. The null hypothesis is represented by the diagonal line.

3.1.3 Prevalence of impaired medical decision-making capacity among geriatric patients with and without dementia

The prevalence of impaired MDC in geriatric patients with AD, MCI and somatically ill, geriatric in-patients was calculated using KIMB's cut-off value. Table 3 shows median, minimum and maximum values for each group assessed with KIMB. The healthy control group showed highest median value, followed by MCI, AD and the group of somatically ill in-patients. The high prevalence of impaired MDC among geriatric patients without known cognitive impairment was the main result from study IV. These participants' mean score on KIMB, 9.3±4.9, was as low as that of the AD group in study III: 11.6±3.6 points. A straightforward explanation for the high prevalence of impaired MDC could be that these patients, despite lacking known cognitive difficulties, nonetheless had at least temporary cognitive impairment as measured by MOCA mean score was 21.2(±3.8) out of 30.

Table 3. Score on Clinical instrument of medical decision-making capacity (KIMB) presented as median, minimum and maximum values for participants in the Healthy control group, Mild cognitive impairment group, Alzheimer's disease group and the group of geriatric in-patients.

	Healthy control group **Mdn(range)**	Mild cognitive impairment group **Mdn(range)**	Alzheimer's disease group **Mdn(range)**	Somatically ill, in-patient group **Mdn(range)**
KIMB	15(12-19)	14(11-19)	13(1-16)	10(0-19)

Looking into prevalence numbers across studies, a similar pattern appeared. Among participants with AD, the prevalence of impaired MDC was 91%, and among the in-patients with somatic illnesses, the prevalence was 86%. Participants with MCI passed KIMB to a greater extent; the prevalence of impaired MDC was 57% in the MCI group. As expected, the healthy control group performed best, but 25% did not attain KIMB's cut-off score. Figure 17 shows how many participants failed/passed KIMB in each group.

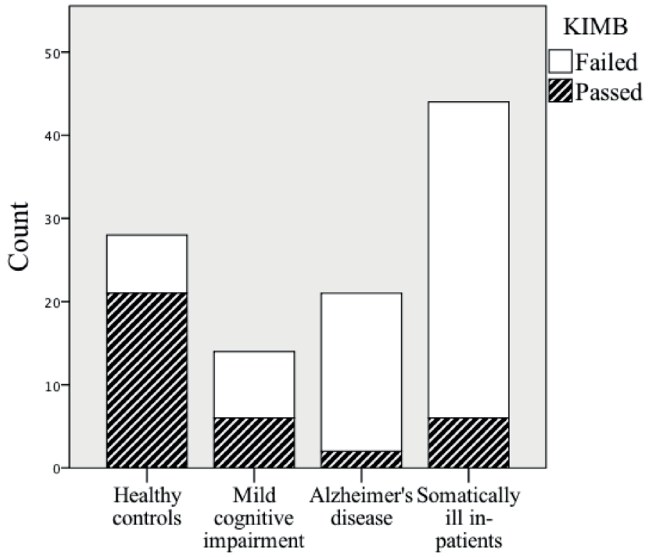


Figure 17. Distribution of how many participants failed and passed Clinical instrument of medical decision-making capacity in each group. Among healthy controls, 75% passed the cut-off score (≥14 p), while in the Mild cognitive impairment group 43% passed. Only 9% of participants with AD passed, and 14% of the somatically ill, geriatric in-patients.

3.2 SUBSIDIARY ELEMENTS TO MEDICAL DECISION-MAKING CAPACITY

This section will present and compare results from study II-IV. Interpretations must bear in mind that even though LIMD and KIMB were constructed from the same definition of MDC, they are two different tests. Furthermore, due to the different characteristics of the data, some correlations were made with a parametric test, Pearson's correlation coefficient *r*, and others with a non-parametric test, Kendall's tau–b, τ. Numbers for sociodemographic factors and cognitive tests are presented in Table 4.

Table 4. Analyses of correlations to medical decision-making capacity (MDC). MDC was either measured with Swedish linguistic instrument for medical decision-making (LIMD) or Clinical instrument of medical decision-making capacity (KIMB). The correlations were calculated either using Kendall's tau–b, τ, or Pearson's correlation coefficient, r.

Socio-demographic factors and tests	Correlations to LIMD score **Study II**	Correlations to KIMB score **Study III**	Correlations to KIMB score **Study IV**
Age	*Non-significant*	*Non-significant*	*Non-significant*
Education	*Non-significant*	τ = .28***	r = .48**
Overall cognition	MMSE[A1], r = .50*	MOCA[A2], τ = .50***	MOCA[A2], r =.58**
DLS Reading speed[B]	r = .42*	τ = .43***	-
Repetition[C]	r = .61**	τ = .46***	-
Inference[D]	*Non-significant*	τ = .36***	-
RAVLT[E]	r = .54**	τ = .37***	-
Word comprehension[F]	-	-	r = .62**
Premorbid overall cognitive function[G]	-	-	r = .69**
Word sequence forward[H]	-	τ = -.20*	-

* = significant at ρ≤.05
**= significant at ρ≤.01
***= significant at ρ≤.001
- = not included in the study
A1: Overall cognition as measured by Mini-mental state examination[138]
A2: Overall cognition as measured by Montreal cognitive assessment[140]
B: DLS Reading speed (also measures understanding)[147]
C: Repetition of long sentences from BeSS[151]
D: Inference from BeSS[151]
E: Rey auditory verbal learning test[152]
F: DLS Word comprehension[147]
G: Irregularly spelled words, a test to estimate premorbid full-scale intelligence quotient[153]
H: Word sequence forward, months of the year[154]

Age was not significantly correlated to MDC in any of study II-IV. Educational level, as measured by years of formal education, was significantly correlated to MDC as measured by KIMB; longer formal education showed a positive, linear relationship to higher score on KIMB. However, no significant correlation was found between educational level and LIMD score.

Overall cognition was significantly correlated to MDC in study II-IV, as measured by MMSE or MOCA. DLS Reading speed, RAVLT, Repetition of long sentences and Inference were used in both study II and III. Higher score on DLS Reading speed was positive, linear and significantly correlated to higher score on KIMB (strong correlation) and LIMD (medium

correlation). Higher score on both RAVLT and Repetition of long sentences both showed strong, positive, linear and significant correlation to KIMB and LIMD. But where Inference showed a strong, positive, linear and significant correlation to MDC as measured by KIMB, no such correlation was found between Inference and LIMD.

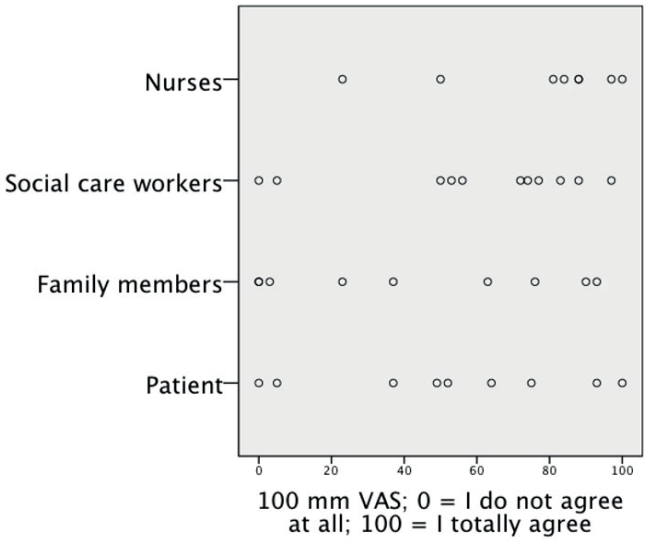
The tests included besides KIMB in study IV assessed potential risk factors for impaired MDC. The results showed that smaller receptive vocabulary and lower estimated premorbid cognitive function were risk factors to impaired MDC. The correlations for each were strong, linear, positive and significant.

3.3 APPROACHES TO FACILITATE MEDICAL DECISION-MAKING

In study I, experiences of communication during discharge meetings were evaluated by patients, family members, nurses and social care workers using Visual analogue scales (VAS). Counter to the hypothesis, the group where patients had been prepared for their discharge meetings using Talking mats (TM) got significantly lower scores on VAS compared to the control group. A two-way ANOVA showed a significant interaction effect between how the different groups of raters (patients, family members, nurses and social care workers; between factor) rated the different statements (within factor). The interaction effect is illustrated in study II, Figure 3. The Talking mats group (TMG) also had a fourth statement to rate: *I think Talking mats has helped communication*. The distribution of ratings on this statement was large in all groups of raters as shown in Figure 18.

There was no significant difference in AD patients' MDC depending on whether original or Adapted vignettes were used. A small but significant difference was found to depend on trial; the participants showed slightly higher scores on LIMD when Kidney disease vignettes were used, compared to when Hypertension vignettes were used.

Figure 18. Ratings on VAS (0-100 mm) to the statement *I think Talking mats has helped communication* given by nurses, social care workers, family members and patients present during the discharge planning meetings. The patient had been prepared using the Talking mats method prior to the meeting. In all groups of raters there was a large range, meaning that some individuals did not think Talking mats helped the communication at all, while others thought it helped a lot.



4 DISCUSSION

4.1 THE EVER-PRESENT ETHICAL DILEMMA

Three ethical aspects have been highlighted concerning research with geriatric participants: 1) respect for person, including the span between promoting autonomy and protecting those who lack medical decision-making capacity, 2) designing studies which maximize potential benefit and minimize potential risks and 3) recruiting participants equitably, meaning that participants should be representative of the population and appropriate for the research questions.[155]

The entitlement to autonomy is enforced globally as well as nationally. All humans are born free and equal, and should be free to make their own decisions.[156] All potential participants should receive adequate information prior to inclusion in order to enable an autonomous decision.[157] Autonomous decisions within health care and research should be actively promoted as far as possible.[158] On the other side of an autonomy spectrum, there is need for caregivers to protect patients who lack decision-making capacity.[159,160]

Impaired medical decision-making capacity, as well as failing participation, have potentially negative consequences for a patient. One risk is that an individual who has not correctly apprehended information given, makes a decision based on incomplete or even incorrect premises. Patients with Alzheimer's disease are at hazard of underestimating risks in medical research.[161] Another problem concerns if a patient is not asked to participate in a study, because of presumed incompetence to give informed consent. Possible explanations might be that caregivers are unsure of how to assess medical decision-making capacity and lack knowledge of current policies.[162] Existing interventions to protect an individual who lacks decision-making capacity are, for example, advance directives, a proxy as a decision-maker or a legally appointed administrator or surrogate decision-maker.[158-160,163-165]

A high level of medical decision-making capacity is required to give informed consent to a clinical trial. Prior to inclusion in medical research, it is important to correctly identify participants at risk of not understanding information given.[166] Even cognitively intact patients and healthy controls may struggle with this type of decision. The written information, likely containing technical terms, requires the potential participant to have a high reading level to correctly interpret and apply the information.

The crux – ensuring that each participant has understood what the research is about – has been present in this doctoral project from start to finish. To indicate that the participants have given their truly informed consent to a study, when the study's results show that a majority of the participants are at immediate risk of impaired medical decision-making

capacity, constitutes a dilemma. All studies included were approved of the Regional ethical committee, Stockholm, and thus followed the legal framework concerning adults with impaired decisional capacity:

- The research questions could not have been answered using other, decisionally competent, participants.
- The research was expected to yield results that would benefit either the patients themselves, or others with the same conditions.
- The research entailed an insignificant risk of injury and an insignificant risk of discomfort.
- Inclusion to the study was done in consultation with the next of kin of patients with dementia.
- The person carrying out the parts of the studies that involved interactions with participants was continously on the lookout for any signs that they did not want to participate.

4.2 DISCUSSION OF METHODOLOGY

4.2.1 Sample and design

Study I has most potential weaknesses regarding design and results. The intention to let participants evaluate aspects of communication on VAS in study IV was valid since patients' experiences are an important aspect of communication and participation. Comparison between groups showed higher ratings for communication quality in the control group than in the Talking mats group. Therefore, it would have been interesting to objectively examine communication and participation during the meetings. An objective analysis based on video recording would have been needed to meet that end. Furthermore, there was no check to see if the Talking mat that was used to prepare the participant was also used during the discharge meeting.

4.2.2 Data analysis and material

Aspects of the vignette in Clinical instrument of medical decision-making capacity (KIMB) were hard to comprehend and appreciate regardless of cognitive status, as shown by the relatively low median score in the healthy control group. During the construction and initial testing of KIMB, healthy individuals got higher scores on KIMB than the healthy individuals examined during study III. An explanation might be found in the different samples. Most of the healthy individuals approached in the construction of KIMB either worked in health care or were speech and language pathology students. It is conceivable that being familiar with technical terms and research procedures could enhance the understanding of a person being asked for consent/assent to participate in clinical trials.

An innovative feature of KIMB was to present a cut-off value, which existing tests that assess medical decision-making capacity using the vignette method do not (MacCAT-CR,[167] UBACC[62] and LIMD[24]). A cut-off indicates that any score below this value should

prompt one or more interventions, for example further assessment, support in medical decision-making processes and addressing a surrogate decision-maker. Lack of a cut-off value may make it more difficult to know how to interpret the result. However, the lack of a cut-off may encourage the assessor to make a holistic evaluation, for example using his/her own clinical judgment.[54]

4.3 DISCUSSION OF INTEGRATED RESULTS

4.3.1 High prevalence of impaired medical decision-making capacity in geriatric patients with and without dementia

An unexpected similarity between the studies in this thesis, was that in-ward patients participating in study IV with an *explicit exclusion criterion* regarding cognitive impairment and acute confusion, showed median KIMB score as low as the median score among patients with Alzheimer's disease. In-ward geriatric patients as a group may be at risk of impaired medical decision-making capacity regardless of whether they are affected by dementia or not; the prevalence number of impaired medical decision-making capacity among somatic in-ward patients was very high, 86%. In previous studies, in-patients without dementia have had reported prevalence numbers between 30-50% of impaired medical decision-making capacity as assessed by MacCAT-T.[52,92,93,168] The in-patients' results gave a snapshot of their medical decision-making capacity. Their capacity may have improved after recovery and discharge. Investigating the prevalence of impaired capacity among other groups of in-patients, but also geriatric out-patients without cognitive impairment would be of interest in future research.

Explanations for the impaired medical decision-making capacity may be found within investigated risk factors. Higher age has been shown in other studies to correlate with lower medical decision-making capacity, although no such correlation was seen in this thesis. Older individuals tend to have shorter formal education, which was correlated to lower scores on medical decision-making capacity within this thesis and elsewhere.[110,131] Other factors not yet addressed need further investigation. Pain of a magnitude that it was obvious that pain affected a patient's general condition was an exclusion criterion. However, no measure addressed pain. Some participants probably experienced pain or discomfort to some degree. Another factor of interest is how tired the patient felt when participating in the study.

4.3.2 Applicability of Clinical instrument of medical decision-making capacity

KIMB is primarily intended to be applied to assess a potential participant's medical decision-making capacity prior to inclusion in a clinical trial. Decisions based on a hypothetical vignette may not accurately reflect a person's capacity regarding information for an actual trial.[58] An advantage, however, is that using a test based on a hypothetical vignette enables researchers to compare scores between settings and diagnoses.[29] A disadvantage is that KIMB requires reading skills, but the test can be completed quickly and is easily corrected.

A theoretical perspective is valuable when discussing applicability of KIMB. In order to have a well-functioning medical decision-making capacity, *all* components should be present. If so, as soon as an individual scores lower than maximum, further assessment or other actions would be needed in the medical decision-making process. The fact that seven healthy controls did not pass the cut-off score, and that only two got 19/19, supports previous studies that also cognitively intact individuals may imperceptibly struggle to give truly informed consent.[131,132,169,170] The difficulties that possibly face even healthy controls may explain why their KIMB scores did not differ from those of participants with Mild cognitive impairment. Another explanation could be that KIMB does not capture subtle variations in medical decision-making capacity.

There are several reasons why a specific assessment of medical decision-making capacity is needed, even though scores typically correlate to screening of overall cognitive function. MMSE underestimated impaired medical decision-making capacity among the elderly individuals in assisted living facilities.[168] A diagnosis of dementia or a score on a screening test cannot be used on individual level to draw conclusions regarding medical decision-making capacity. KIMB gives a standardized measure and indicates which aspects an individual struggles with. The specific deficiencies detected can indicate where further actions are needed. The test result can be used to explain strengths and difficulties to all parties involved in the decision-making process, like patient and next of kin. However, it may be ethically problematic to test a person before he/she has consented to participate in a study.

Using KIMB in study IV gave a first glimpse of its applicability in a clinical setting. In view of the discrepancy noted between clinicians when subjectively judging a patient's medical decision-making capacity,[171] it could be argued that it could be better to use KIMB than to rely solely on subjective judgment, even though it is intended for use in the context of informed consent in clinical trials. But of course, this would be up to each clinician to decide, as well as how to act as depending on a patient's score.

4.3.3 Communication: difficulties and opportunities in medical decision-making processes

The Adapted vignettes had a linguistic construction that was in some but not all ways simpler than in the original vignettes as analyzed by SVIT. In order to keep ecological validity, it was important that relevant information regarding risks and treatment was kept in the Adapted vignettes. However, LIMD scores did not increase. One explanation could be that the participants were too affected by cognitive impairment to benefit from this kind of support.

The results in study II have important implications; even though the information was *specifically* adapted to be more easily comprehended by patients with AD, these individuals still exhibited *extensive* impairments in medical decision-making capacity. While the use of

"plain language" has been suggested as way to increase participants' understanding of information given prior to inclusion in a clinical trial,[172] the results of study II suggest that this is not a valid strategy for geriatric patients with dementia.

Several interpersonal factors were found to be related to medical decision-making capacity within the studies: *age* and *formal education* have already been mentioned. In addition, positive correlations were found to *overall cognitive function*. Since medical decision-making capacity is a multi-faceted cognitive function, correlations to screening tests of overall cognitive function could be expected. Indeed, overall cognition can be the most well-documented predictor for medical decision-making capacity.[25] Positive, significant correlations to *DLS Reading speed*,[147] *RAVLT*[152] and *Repetition of long sentences*[147] followed the same pattern as previously published correlations to LIMD.[32] A compilation of interpersonal factors affecting medical decision-making capacity, based on integrated results, is found in Figure 19.

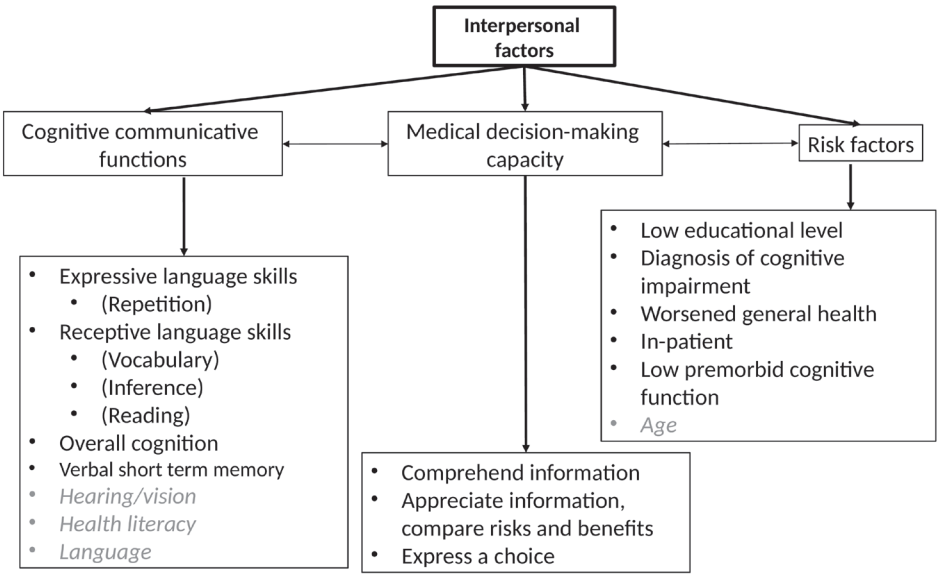


Figure 19. Interpersonal factors with relationships to patients' medical decision-making capacity based on integrated results (inclusion/exclusion criteria in italics).

5 A PROPOSED MODEL TO STANDARDIZE INFORMED CONSENT PROCEDURES

Medical decision-making processes can be difficult to participate in for in-ward geriatric patients regardless of whether a neurodegenerative process is present or not. Medical decision-making capacity is also affected early in Alzheimer's disease. The ability to give informed consent cannot be taken for granted in the geriatric patient group. Formal caregivers have the responsibility to support patients to participate as best they are able in their own medical decision-making.

Researchers frequently ask patients to consent to participate in a study, but a standardized method which emphasizes each individual's right to understand information and make an autonomous decision is lacking. Figure 20 presents a suggested standardized procedure for inclusion to medical research. The aim of the flowchart is to promote best possible participation in the decision-making and most clearly discern the free will of each geriatric patient, based on a communicative approach. A Swedish version is found in Figure 21. In future studies, it would be of interest to examine if this flow-chart can help researchers exercise their responsibilities during medical decision-making processes, and what consequences that has for geriatric participants and their next of kin.

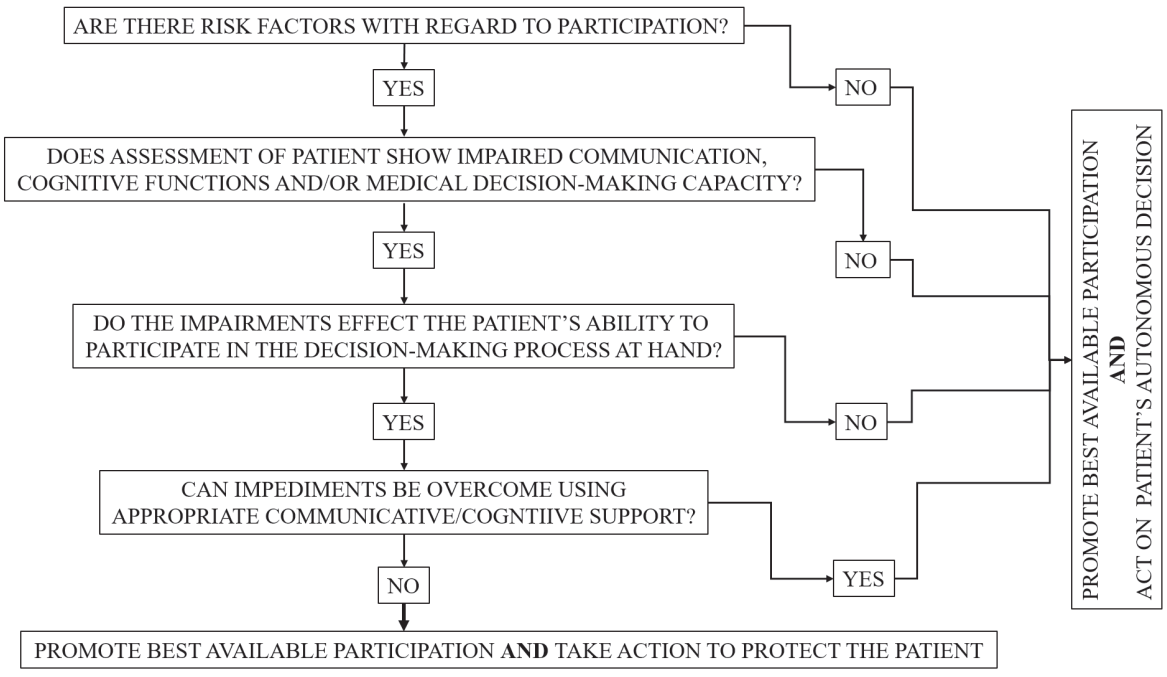


Figure 20. Suggested standardized process for researchers when asking geriatric patients for informed consent to participate in a clinical trial.

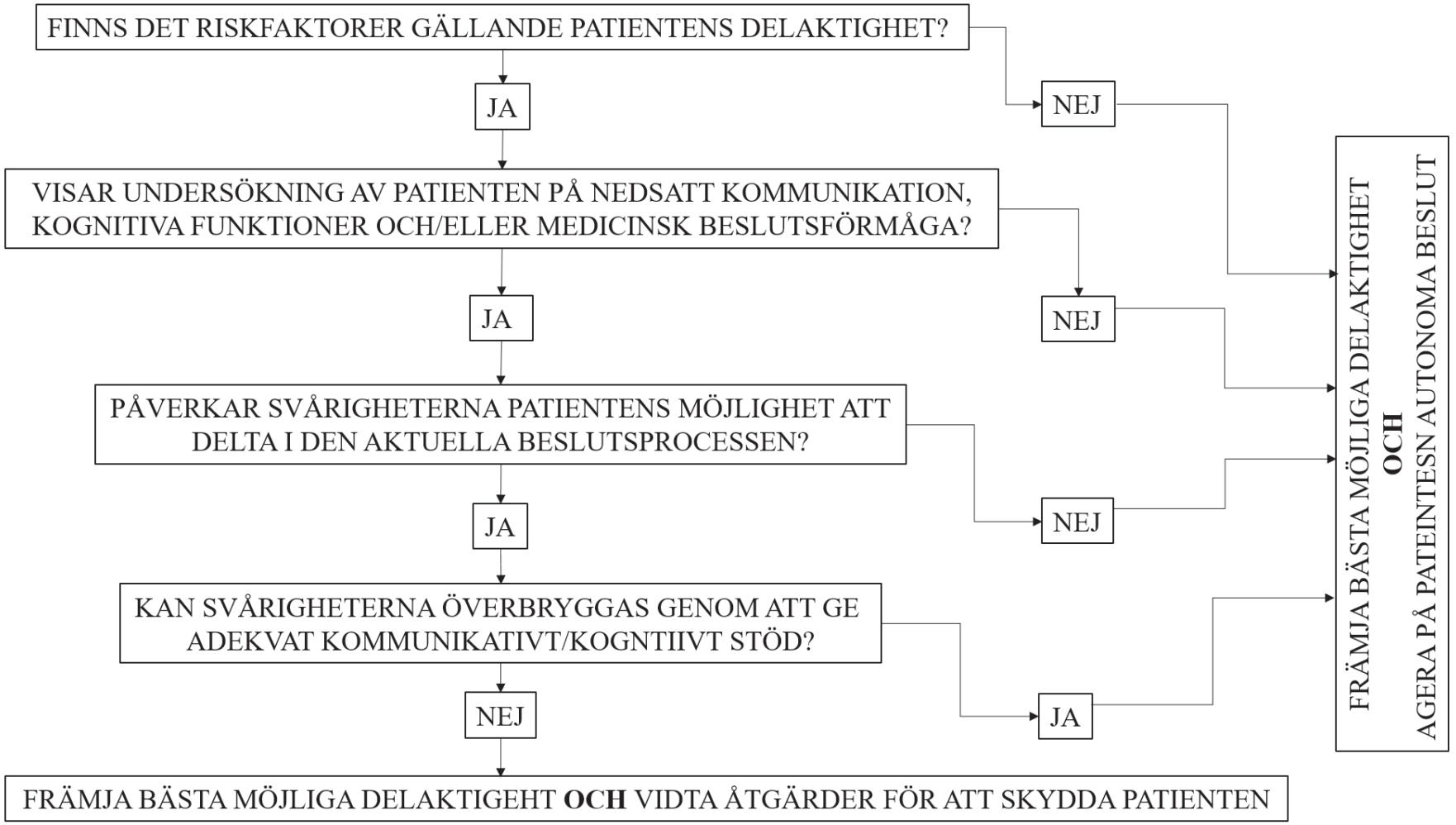


Figure 21. Förslag på ett standardiserat förfaringssätt när forskare efterfrågar en geriatrisk patients informerade samtycke för att delta i medicinska studier.

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ACKNOWLEDGMENTS

Det är många som har hjälpt mig under mina doktorandstudier och avhandlingsarbetet. Först och främst vill jag tacka **Ann Malmenholt**. Vi antogs som doktorander med bara några månaders mellanrum, och du har följt mig genom hela denna resa. Du är smart, du har stor kunskap och jag har lärt mig så mycket genom våra diskussioner. Dessutom har du lagt ner tid och engagemang på att ge mig feedback på allt från webbinarier till de ingående studierna. Mest av allt är jag glad över att få ha dig inte bara som kollega utan också som vän.

Till min huvudhandledare **Ing-Mari Tallberg** riktar jag också ett stort, varmt tack. Det var tack vare din uppmuntran jag överhuvudtaget vågade ta steget att bli doktorand. Du har låtit mig ta ansvar och utvecklas. På många olika sätt har du klokt guidat och format mig in i min blivande forskarroll. Min bihandledare **Katarina Heimann Mühlenbock** vill jag också rikta ett varmt tack till. Du vågade bli min handledare efter, om jag minns det rätt, två telefonsamtal och ett fysiskt möte. Du har generöst delat med dig av din specialkunskap om läsbarhet och din egna metod SVIT. Det har varit värdefullt att få bolla stort som smått med dig. Till min andra bihandledare, **Erik Sundström**, vill jag också rikta ett stort tack. Din handledning och återkoppling på manuskript har alltid varit genomtänkt och manat till fortsatta funderingar. Jag vill också tacka **Bengt Jacobsson** för att du i din egenskap av min mentor alltid haft en stund att avsätta när det har behövts.

Arbetet med avhandlingen hade förstås aldrig gått att genomföra om det inte vore för alla deltagare i de olika studierna, tack! Dessutom vill jag särskilt tacka alla hitintills inte omnämnda medarbetare i studierna: **Ove Almkvist** för värdefull hjälp med statistisk bearbetning, **Maria Eriksdotter** för samarbete med rekrytering av patienter från minnesmottagningen tillsammans med **Jacob Holmér**, och **Sara Stormoen** för allt samarbete kring KIMB. Tack **Lars Robertsson** för värdefullt stöd och hjälp i planeringen av den sista studien. **Roxanne Harris** och **Eric Levander**, tusen tack för hjälpen med de deltagare som ni rekryterade och testade. Det var lärorikt att få vara bihandledare för ert examensarbete. Tack också till **Daniela Gabrielsson** för den gedigna ombearbetningen av vinjetterna i LIMD.

Jag vill också tacka följande starka kvinnor och kollegor för att ha gått vägen före mig och generöst delat med er av kunskap och erfarenheter: **Päivikki Aarne, Gunilla Henningsson, Kerstin Johansson, Ulrika Nygren** och **Maria Södersten**. Ni är mina förebilder! Tack **Anette Lohmander** för ditt stöd och ditt engagemang, och allt du lärt mig om vetenskaplig metodik. Jag vill också passa på att tacka övriga medarbetare på Enheten för Logopedi: **Anita McAllister, Anna Eva Hallin, Britta Hammarberg, Marion Lieberman, Jill Nyberg, Ellika Schalling, Sofia Strömbergsson** och **Per Östberg**. Inte minst genom forskningsseminarierna har jag fått bra feedback på mina projekt, och även fått lära mig så mycket av att få ta del av andras.

Tack till mina kollegor och vänner på Karolinska universitetssjukhuset för visat intresse, stöd och inspiration: **Sanna Jansson, Fredrik Sand, Georgia Tsipra** och **Catarina Wersch**. Tack **Elisabeth Lundström** och **Caroline Björck** för er uppmuntran och ert stöd i att hitta konstruktiva lösningar för att kombinera mitt kliniska arbete som logoped med doktorandstudierna.

Agneta Wittlock, tusen tack för all hjälp med LADOK, årliga uppföljningar och allt annat du har hjälpt mig med under dessa år. Din insats för att fixa layout till avhandlingen var ovärderlig, tack! Tusen tack **Christina Hedestedt** för allt stöd, hjälp med papper och administration! Jag vet inte vad jag skulle ha tagit mig till utan er! Dessutom vill jag tacka **Daniel Lindsäth** som agerade räddare i nöden och språkgranskade manuskript två, samt **Janet Holmén** som språkgranskade ramberättelsen och gav mig viktiga insikter om hur vetenskap kan förmedlas till såväl granskare av ansökningar som till lekmän.

Slutligen vill jag tacka min familj och vänner för allt stöd jag fått, ensam är inte stark!

The projects has generously been funded by

- Stockholm county council (Stockholms läns landsting, ALF-medel)
- Stockholm county council fund for care development at the Karolinska University Hospital (Karolinska universitetssjukhusets vårdutvecklingsfond)
- Regional agreement on medical training and clinical research (FoUU) between Stockholm county council and Karolinska Institutet
- The Aina Börjeson foundation (Aina Börjesonfonden)
- The foundation for Old servants (Stiftelsen gamla tjänarinnor)
- The Solstickan foundation (Stiftelsen Solstickan)

”There’s still so much to do; still so much to learn.”

– Jean-Luc Picard,

Star Trek: Next Generation, Season 1, Episode 26