Reliability and Validity of the Evaluation to Sign Consent Measure

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Purpose: The purpose of this report is to evaluate the reliability and validity of the five-item Evaluation to Sign Consent (ESC), a measure that can guide determination of an older adult’s capacity to consent for research. Design and Methods: Information was obtained from 346 nursing home residents from six facilities who were being enrolled into a randomized controlled trial testing a restorative care intervention. In addition to the ESC, the resident’s cognitive status and demographic information was obtained. Results: The average age of the participants was 86.1 ± 7.3 years; most of the participants were female (84%) and Caucasian (95%). The mean Mini-Mental State Exam score was 18.0 ± 7.4. A total of 218 residents (63%) did not pass the ESC. According to a Rasch analysis and the inter-rater reliability (r = .81), there was some evidence of reliability and validity with this measure. Logistic regression showed that Items 1 (describing two risks to participation in the study) and 2 (knowing what is associated with participation) had the greatest overall percentage of agreement with the full ESC, and the Mini-Mental State Exam was the only resident-tested variable to predict the results of the ESC. Implications: This study provides useful information about the ESC. It indicates a reason and a method to move beyond cognitive testing that can more appropriately evaluate the capacity to consent to participate in research.

Key Words: Recruitment, Consent, Nursing homes, Research participants

Nursing homes have not received the level of scientific study that other areas of health care have. This is unfortunate, given the ongoing concerns about the quality of care in nursing homes and because increased demand will result in an estimated 3.6 million older adults requiring these services by 2018 (National Institute on Aging, 1997). To provide the best possible care to these individuals, it is crucial to include all nursing home residents in studies that describe their care needs and outcomes as well as those that test interventions that will optimize health, function, and quality of life.

One of the challenges in conducting nursing home research is the ethical issue surrounding consent. Nursing home residents are generally considered frail and vulnerable, largely because at least 50% of them have some degree of cognitive impairment (Gruber-Baldini, Zimmerman, Mortimore, & Magaziner, 2000). Thus, issues related to decision-making capacity are common and questions often arise related to participation in interventions. As previously defined by Karlawish, Casarett, and James (2002), “capacity” refers to a person’s performance on measures of decision-making abilities (such as understanding). Taking this one step further, Karlawish and colleagues define “competency” as a judgment that the individual’s capacity is adequate to make the decision he or she has made. Capacity issues and the ability to provide informed consent extend to the residents’ participation in any type of research, but this concept has not been critically examined in the literature. Considering that recent studies have determined that even moderately cognitively impaired individuals have the capacity to respond to questions about end-of-life care decisions (Mezey, Teresi, Ramsey, Mitty, & Bobrowitz, 2000) and quality of life (Brod, Stewart, Sands, & Walton, 1999), we find it appropriate to consider if cognitively impaired individuals have the capacity to consent to participate in research.

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impairment. Additionally, safeguards, such as the use of advanced directives for research, may be necessary when greater than minimal risk is involved.

Table 1. National Institutes of Health Recommendations for Conducting Research With Cognitively Impaired Individuals

<table>
<thead>
<tr>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. The consent process must clearly differentiate between accepted treatment and research.</td>
</tr>
<tr>
<td>2. The Institutional Review Board should include at least one member who is independent of the proposed research project and has expertise in issues of decisional capacity.</td>
</tr>
<tr>
<td>3. Adequate assessment of participant capacity must be addressed in the research protocol.</td>
</tr>
<tr>
<td>4. There should be safeguards for the additional protection of participants as the severity of impairment increases.</td>
</tr>
<tr>
<td>5. Ongoing education should be conducted to enhance participant understanding.</td>
</tr>
<tr>
<td>6. Additional safeguards, such as the use of advanced directives for research, may be necessary when greater than minimal risk is involved.</td>
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Omnibus Budget Reconciliation Act of 1987

A component of the OBRA of 1987 (OBRA Guideline), The Residents Bill of Rights, directly addresses research. Specifically, this section of the OBRA Guideline provides guidance for how residents should be treated, which includes their involvement in research studies. For example, residents have the right to choose their treatment and to have their needs accommodated; certainly, participation in or refusal to participate in clinical trials should be considered each resident’s right.

Researchers in nursing homes must carefully address the rights afforded to all human subjects in the research process: informed consent without coercion, the ability to withdraw from participation in a research study without any negative ramifications, assurance of protection from harm and financial burden, and a guarantee to uphold dignity and privacy (Touitou, Portaluppi, Smolensky, & Rensing, 2004). Researchers must ensure disclosure and comprehension when presenting information to a potential participant, and potential participants must be competent and have the ability to decide voluntarily. Therefore, the actual process of obtaining informed consent requires that all relevant information gets conveyed, the environment remains noncoercive, and the participant has the capacity to make a decision on his or her own behalf. It is this latter component that is the focus of this article.

Recommendations From the National Institutes of Health

In an attempt to protect vulnerable research participants, such as those living in nursing homes, the National Institutes of Health established recommendations for researchers to follow when doing research with cognitively impaired individuals (Table 1). These guidelines provide protection for residents at the time of the consent process and throughout the course of the research study. For example, consideration is given to possible changes in participants’ cognition over the course of the study and a process for reevaluation and a plan for reassessing the individuals’ understanding are suggested.

Case Law and Research Relevant to Capacity to Consent

It is important to differentiate between informed consent for research, the focus of this report, and consent for treatment. Participants involved in clinical research studies should understand the difference between treatment and research protocols, the latter of which include such things as randomization to different treatment arms and the use of placebos. In addition, they need to understand that they may or may not benefit directly from the experimental intervention (Dunn & Jeste, 2001). By law, decisional capacity, and the ability to consent or refuse to consent to participate in research, is predicated on four elements (Applebaum & Grisso, 1995; Marson, Ingram, Cody, & Harrell, 1995). The first is having the understanding or the ability to comprehend the disclosed information about the nature and purpose of the study, the procedures involved, and the risks and benefits of participating versus not participating. The second is having an appreciation of the significance of the disclosed information and the potential risks and benefits for one’s own situation and condition. The third is having reasoning, which involves the ability to engage in a reasoning process about the risks and benefits of participating in the proposed research versus alternatives to participation. The fourth is having choice, or being able to choose whether or not to participate.

Although selected neuropsychiatric tests and cognitive screening tests have been associated with decision-making capacity (Casarett, Karlawish, & Hirschman, 2003), there are no cognitive screening tests that clearly establish residents’ decision-making capacity (Allen et al., 2003; Kim, Karlawish, & Caine, 2002; Mezey, Mitty, & Ramsey, 1997; Moye, Karel, Azar, & Gurrera, 2004). Moreover, a combination of screening tests and vignette-based measures has been found to result in errors in determining capacity in one third of residents (Pruchno, Smyer, Rose, Hartman-Stein, & Henderson, 1995). Physicians tend to be more lenient in their judgment of...
resident capacity, whereas family members are more stringent (Vellinga, Smit, Van Leeuwen, Van Tilburg, & Jonker, 2004). This discrepancy could be because clinicians evaluate capacity on the basis of cognitive status (Williams & Engles, 1995), whereas family members depend on less clinical information. Moreover, there may be differences in the determination of capacity because of the different methods and tests of determination that are used. Three such measures are described here.

In an attempt to specifically evaluate the capacity to consent to research, researchers developed the MacArthur Competence Assessment Tool—Clinical Research Version (MacCAT-CR; Applebaum & Grisso, 2001; Kim, Caine, Currier, Leibovici, & Ryan, 2001). This tool contains 21 disclosure elements of informed consent that fall under the four abilities of capacity previously described (understanding, appreciation, reasoning, and choice). For each item, there is a response rating of 0 (inadequate), 1 (partial), or 2 (adequate). The MacCAT-CR is administered by means of a semi-structured interview that is adapted to reflect the specific research protocol being addressed. Of the 21 items, 13 focus on understanding of the research, 3 focus on appreciation or the participants’ ability to apply what they have been told about the study to themselves, and the remaining 5 address reasoning and the participants’ ability to compare research participation with other treatment options. This tool has been used with individuals with schizophrenia (Carpenter et al., 2000; Dunn, Palmer, Kehaa, Jeste, & Appelbaum, 2006), depression (Applebaum, Grisso, Frank, O’Donnell, & Kupfer, 1999), Alzheimer’s disease (Kim et al.; Karlawish et al., 2002), and cancer (Aaronson et al., 1996; Casarett et al., 2003; Simes et al., 1986), and it has provided some evidence of internal consistency and validity (Dunn et al.; Karlawish et al.; Kim et al.).

Saks and colleagues developed the California Scale of Appreciation (CSA; Saks et al., 2002) to specifically assess the appreciation aspect of capacity, and it establishes if potential participants can form adequate beliefs about how the information provided applies to them. The CSA involves having participants respond to 13 close-ended questions and 5 open-ended questions after they have read a consent form. Although there is some evidence of the reliability of this measure, there are concerns about its validity, as Saks found that the majority of participants were fully capable to consent (Saks et al.).

The Evaluation to Sign Consent (ESC) is a brief five-item questionnaire that evaluates the individual’s capacity (DeRenzo, Conley, & Love, 2001). It was developed in response to previous findings that suggested that study participants could not correctly state the purpose of the research study in which they had consented to participate (Dunn & Jeste, 2001; Sugarman, McCrocry, & Hubal, 1998; Appelbaum & Roth, 1982). The intent of the ESC therefore is to assess whether a participant’s factual understanding of information is sufficient to provide ethically valid consent to participate in a specific research study. No psychometric properties have been published on this tool, although it has been used in multiple studies with schizophrenia patients (DeRenzo et al.). The focus of this report is on the use and psychometric testing of the ESC.

Institutional Review Boards’ Recommendations

In light of concerns about capacity to sign consent, some IRBs are beginning to require that a set of questions be asked of potential study participants to establish capacity. If an individual can demonstrate an understanding of the research study and the impact that participation will have on her or him, then capacity is assumed and consent to participate can proceed, regardless of underlying cognitive ability. Because of the high rate of cognitive impairment in some nursing home residents, having a standardized assessment is a welcomed addition in nursing home research (Magaziner et al., 2000). Although different approaches to ascertain the residents’ capacity have been suggested (Cleary, 2004; Powers, 2003), there is no gold standard that fully ensures this.

In this article we report on the reliability, validity, and utility of the ESC (Appendix A), one of several assessment tools permitted by the IRB of the University of Maryland School of Medicine. For studies employing the ESC, the IRB requires potential study participants to complete the ESC prior to completing the consent process. Residents who pass the ESC (answer all of the items correctly) are invited to provide their own consent to participate. Those who are unable to pass the ESC but verbally consent and express a willingness to participate in the study are asked to sign an assent form. The proxy of such residents is then contacted to complete the consent process. The ESC focuses on only an understanding of the research, and although it has been used in clinical research there is no published evidence of its reliability and validity (DeRenzo et al., 1998). Thus, our purpose in this article is to evaluate the reliability and validity of the ESC. In addition, we assessed the predictive ability of each ESC item and the predictive ability of cognitive status and demographic variables on the residents’ capacity to sign consent. Findings are useful in providing guidance to researchers working with residents in any long-term-care or community setting.

Methods

Design

We trained and involved a total of 10 research evaluators in the process of recruiting residents into...
or she may sign the consent form. If the resident fails the ESC, then proxy consent is needed. About an answer, call the Project Coordinator or Field Staff Coordinator. Sign and date the bottom; no witness signature is necessary merely repeat what you say; they must understand the consent form (i.e., respond in their own words). If you have a question are asking. If a resident states something such as "I don't remember," you can read that section again. Residents should not say "no." The resident will not be considered eligible. The questions can be rephrased so the resident can understand what it is you are asking. If a resident states something such as “I don’t remember,” you can read that section again. Residents should not merely repeat what you say; they must understand the consent form (i.e., respond in their own words). If you have a question about an answer, call the Project Coordinator or Field Staff Coordinator. Sign and date the bottom; no witness signature is necessary. If the resident answered all of the questions correctly and he or she is not declared legally incompetent in the chart, then he or she may sign the consent form. If the resident fails the ESC, then proxy consent is needed.

During monthly evaluator team meetings, noted discrepancies were discussed.

**Participants**

The analyses in this report include data from the first 346 residents in six nursing homes who were approached and consented to participate in the Res-Care study. Residents completed the ESC and, if we obtained consent from a resident or her or his proxy, we administered the Mini-Mental State Exam (MMSE) to determine if the resident was eligible to participate in the Res-Care study (a cutoff point of 11 was a criterion of study eligibility). Residents not approached to take the ESC, as they were not eligible for the Res-Care study, were those who had a life expectancy of less than 6 months based on documentation by the resident’s primary health care provider, or those who were admitted to the facility for short-stay rehabilitation (anticipated stay less than 4 months).

**Measures**

In addition to using the ESC, we evaluated the resident’s cognitive status (using the MMSE) and abstracted information regarding age from the nursing home chart.

**The ESC.** — The ESC is a five-item measure with an opening question that is not scored, which is used simply to indicate if an individual is alert and able to communicate. The five items reflect the participant’s ability to name at least two potential risks incurred as a result of participating in the study; name two things that will be expected of him or her related to participation; explain what he or she would do if no...
longer interested in participating in the study, or if
distress or discomfort was experienced associated
with study participation; and explain the randomiza-
tion process. For the purposes of our research,
evidence of ability to sign consent was based on
correct responses to all five items on the ESC.

**Mini-Mental State Examination.**—We evaluated
participants’ cognitive status by using the MMSE
(Folstein, Folstein, & McHugh, 1975). Because we
did not know the education level of the participants,
in our analyses we used a cutoff score of less than 20
dichotomize the MMSE score to be indicative of
those with or without moderate impairment (Mur-
den, McRae, Kaner, & Bucknam, 1991).

**Data Analysis**

We performed descriptive analyses to describe the
sample, the cognitive status of participants, and the
results of the ESC. Our reliability and validity testing
of the ESC was based on Rasch analysis, and we
conducted this by using the Winsteps program. We
used the Rasch analysis over traditional methods of
reliability and validity testing, because this analysis
is able to match the individuals’ ability with the
difficulty of the item and the individual standard
error is considered versus the sample or test average.
This results in a more accurate evaluation of internal
consistency. Rasch analysis is based on the assump-
tion that individuals with high or low scores have
less error variance than those with scores near 50%.
That is, individuals are more likely to get a challeng-
ing item incorrect than they are a less challenging
item. Validity estimates are also improved by the use
of model testing. The unidimensionality of the model
can be evaluated along with the fit of each item,
while matching the individuals’ ability and the item
difficulty. A detailed description of Rasch measure-
ment is available elsewhere (Smith & Smith, 2004).

**Validity.**—We based validity on evidence of the
unidimensionality of the measure, the fit of each of
the items to the overall tool, and item mapping
(Smith & Smith, 2004; Waugh & Chapman, 2005).
Item mapping lists the items from most difficult to
derive (i.e., to get correct) to those that are easiest
or most likely to be endorsed in the sample tested.
In addition, item mapping provides a distribution of
individuals responding correctly to questions along
the continuum from the easiest to the most difficult,
so that the researcher can evaluate how well items
discriminate those individuals who might be partic-
ularly high or low on a trait (i.e., capacity). The Infit
and Outfit reflect the fit of the items to the model.
These statistics are acceptable if they are in a range
from 0.6 to 1.4 (Smith & Smith). An Infit and Outfit
value of less than 0.6 indicates that the item does not
provide additional information beyond the rest of the
items on the scale. An Infit and Outfit value greater
than 1.4 indicates that the item does not define the
same construct as do the rest of the items in the
instrument, is poorly constructed or misunderstood,
or is ambiguously defined (Linacre, 2004). Outfit
statistics are sensitive to a few off-targeted unlikely
responses (i.e., a large logit difference between an
item’s difficulty and the person’s ability). The Infit
statistic weighs the squared standardized residual by
the individual variances and is therefore not as
influenced by unanticipated responses; thus, Infit
statistics are more relevant to the utility of a measure.

**Reliability.**—We based reliability of the ESC on
an estimate of the person-fit statistics that consider
each person’s “true” ability. Item-fit statistics, which
are similar to the traditional measurement of internal
consistency, provide a measure of the “true”
difficulty of each item. We based inter-rater re-
liability of the ESC on consistency in scoring by the
initial evaluator and a second trained evaluator.

**The Predictive Ability of Demographic Variables,
Cognitive Status, and ESC Items.**—We tested two
logistic regression models of capacity. One model
considered the percentage of cases for which capacity
was correctly predicted by each individual ESC item.
The other considered the percentage of cases for
which capacity was correctly predicted by demo-
graphic variables (age and gender) and cognitive
status. We used binary logistic regression using a for-
ward conditional entry method to obtain the positive
predictive value and the negative predictive value of
each item or variable, and we used a value of \( p < .05 \).

**Results**

This report is based on the findings from 346
residents who consented to participate from six
different nursing homes. The overall mean MMSE
was 18.0 ± 7.4. The majority of the participants
were female (84%) and Caucasian (95%). The
average age of the participants was 86.1 ± 7.3 years.
A total of 218 residents (63%) did not pass the
ESC. Responses to individual items are shown in
Table 3. Approximately 80% of the participants
could state what to do if they wanted to withdraw
from the study or if they were experiencing pain or
discomfort associated with participation. Approxi-
mately 50% of the participants could name two
things that were expected of them as participants in
the study and state two risks associated with partic-
ipation; 57% could explain treatment assignment.

**Validity and Reliability**

Our analysis of the Rasch measurement model of
the ESC showed that the tool was unidimensional
based on a principal component factor analysis of the residuals (Smith & Smith, 2004). Infit statistics for all items showed a good fit ranging from 0.81 to 1.09. The Outfit statistics for three items (being able to state the risks associated with participation, and what to do if the person was distressed by participation or if he or she no longer wanted to participate in the study) had higher than desirable fit statistics, with all items being greater than 1.4 (Table 3). Item mapping (Figure 1) showed that there was a good spread of the items across the full continuum of ability to pass the ESC. The measure was not able to discriminate individuals who were particularly high or low in their ability to consent, however. This is described in Figure 1 by the number of participants (indicated by the pound signs to the left of the dotted line) who scored above or below all of the items labeled to the right of the dotted line. Consistent with Table 3, the most difficult item to endorse was Item 1, being able to state two risks associated with participation; next was Item 2, the expectations of participation; and third was Item 5, being able to explain how treatment groups were assigned. The easiest items to endorse were Items 3 and 4, which relate to a person’s being able to state what to do if no longer interested in participating or if feeling distress associated with participation.

The person reliability of the ESC was 0.64 with a separation index of 1.33. Item reliability was 0.81 with a separation index of 9.77. Inter-rater reliability, based on total scores on the ESC and using a Pearson correlation, was 0.81. Assumed capacity to participate in the consent process by the field evaluators was based on answering all five items correctly. There was agreement in the determination of capacity, or the pass–fail rates of the ESC, with the second reviewer in 312 of the cases (90%).

Predictive Ability

Results of the logistic regression analyses are presented in Table 4. The item that asks the patient to explain what he or she would do if he or she is experiencing distress or discomfort (Item 4) did not significantly enter the model or predict being able to sign consent. All other items did predict capacity to sign consent. For example, the item asking the patient to explain at least two things that will be expected of him or her in terms of participant cooperation during the study (Item 2) had a positive predictive value of 99%, a negative predictive value of 78%, and an overall percentage of agreement of 93%. Cognitive status, based on MMSE score, was the only demographic variable to significantly predict capacity ($\chi^2 = 49.9, p < .0001$), with a positive predictive value of 84%, a negative predictive value of 52%, and an overall percentage of agreement of 65%. Age ($\chi^2 = 0.02, p = .99$) and gender ($\chi^2 = 0.31, p = .57$) did not significantly enter the model.

Evaluator Survey Results

There was general consensus among the evaluators that completion of the ESC was beneficial to the consent process. It provided the evaluators reassurance that the residents understood to what they were consenting. This assurance was important, as there were instances in which the resident’s chart indicated

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Table 3. Frequency of Responses on the Individual Items of the ESC and Fit Statistics

<table>
<thead>
<tr>
<th>Item</th>
<th>Frequency (%)</th>
<th>Infit</th>
<th>Outfit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name at least 2 potential risks incurred as a result of participating in the study (Risk)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correct</td>
<td>163 (47)</td>
<td>1.09</td>
<td>2.06</td>
</tr>
<tr>
<td>Incorrect</td>
<td>183 (53)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Name at least 2 things that will be expected of him or her in terms of patient cooperation during the study (Expect)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correct</td>
<td>176 (51)</td>
<td>0.81</td>
<td>0.92</td>
</tr>
<tr>
<td>Incorrect</td>
<td>170 (49)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Explain what he or she would do if he or she no longer wished to participate in the study (Withdraw)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correct</td>
<td>281 (81)</td>
<td>0.91</td>
<td>1.99</td>
</tr>
<tr>
<td>Incorrect</td>
<td>65 (19)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Explain what he or she would do if he or she was experiencing distress or discomfort (Discomfort)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correct</td>
<td>291 (84)</td>
<td>1.06</td>
<td>2.26</td>
</tr>
<tr>
<td>Incorrect</td>
<td>55 (16)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Explain treatment assignment or randomization process (Assign Treatment)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correct</td>
<td>198 (57)</td>
<td>0.90</td>
<td>0.90</td>
</tr>
<tr>
<td>Incorrect</td>
<td>148 (43)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total ESC results</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Passed</td>
<td>128 (37)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Failed</td>
<td>218 (63)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: ESC = Evaluation to Sign Consent.
capacity that was not supported by her or his performance on the ESC. Evaluators did recognize, however, that the completion of this measure added time to the recruitment process and frustrated and upset some of the participants, possibly resulting in their decision not to participate in the study.

Discussion

The findings from this analysis provide some beginning support for the validity and reliability of the ESC as a measure to establish capacity to consent to research. Likewise, these findings support prior research and policy that has noted that age is not synonymous with decisional capacity (Kim, Applebaum, Jeste, & Olin, 2004; Moye et al., 2004; Rabins, 1998). Moreover, the findings support the current trend of some IRBs to require screening tools such as the ESC to ensure that older individuals, with or without dementia, can independently decide whether to participate on the basis of their capacity to understand to what they are consenting.

The completion of the ESC does add additional time to the consent process for a group of individuals who may have limited ability to concentrate as a result of both physical and cognitive problems. The time involved, however, is less than that required for the 21-item MacCAT-CR or the 18-item CSA. In addition to the time for completion, the three available tools to measure capacity differ with regard to the inclusion of specific elements that predicate capacity: understanding, appreciation, reasoning, and choice. The MacCAT-CR has the advantage of considering understanding, appreciation, reasoning, and choice related to capacity; the CSA solely addresses appreciation; and the ESC addresses understanding. In response to prior findings (Appelbaum & Roth, 1982; Dunn & Jeste, 2001; Sugarman et al., 1998) that the majority of research participants are unable to correctly describe the research to which they consented (i.e., did not seem to be understanding), the ESC intentionally focuses on understanding. Future research needs to compare these measures and establish if all elements of capacity should be considered or whether a measure such as the ESC, which focuses only on understanding, is sufficient to determine capacity to consent to participate in research.

In addition to providing some evidence for the reliability and validity of the ESC, the Rasch analysis provided some support for the utility of the items in the ESC. The items fit the model particularly well with regard to Infit statistics, or when the item matched the individual's ability. The Outfit statistics are generally believed to be less critical to the establishment of validity, as they are focused on sensitivity in instances when there is a large difference between an item's difficulty and the person's ability. The larger Outfit statistics noted in the use of the ESC may be due to the situation in which...
individuals guessed correctly at the answer, which is likely to be prevalent in this population (Nedjam, Devouche, & Dalla Barba, 2004). According to the Rasch analysis, the most difficult items to answer correctly were asking the patient to name at least two potential risks incurred as a result of participating in the study (Item 1) and asking the patient to name at least two things that will be expected of him or her in terms of patient cooperation during the study (Item 2). It is these more difficult items to endorse that also seem to be the best predictors of capacity based on logistic regression. Specifically, Items 1 and 2 had the largest percentage of agreement with the full ESC. Future research should test a more parsimonious measure of capacity using only these two items, as it is possible that they may be sufficient to determine capacity. In addition, researchers who solicit consent might be advised to more clearly and sufficiently describe these components during the consent process. Future work should standardize the study explanation so that each evaluator provides the same information to each potential participant.

Increased understanding and integration of optimal methods for teaching new information to older adults, particularly those with cognitive impairment, could be used to establish the scripted procedure.

Study Limitations

As with all projects, there were some limitations to this project. The first is the homogeneity of the sample: all participants were in nursing homes and most were female and Caucasian, not known to have a life expectancy of less than 6 months, and not admitted for short-stay rehabilitation. Moreover, although the mean MMSE score was 18, indicative of moderate cognitive impairment (Hirschman, Xie, Feudtner, & Karlawish, 2004), only 18% of those individuals approached were severely impaired (MMSE < 11). Future research should consider using the ESC among a more heterogeneous sample of older adults with regard to demographic characteristics and cognitive ability.

Despite these limitations, this study provides useful information about the ESC. It indicates a reason and a method to move beyond cognitive testing to appropriately evaluate an individual with regard to his or her capacity to consent to participate in research. It is possible that a single item from the ESC (“name at least 2 things that will be expected of her or him in terms of patient cooperation during the study”) may be sufficient to correctly predict capacity to consent, based on understanding of the research, at least 93% of the time. If used in this manner, it could constitute a simple and standard screen in an area that sorely lacks guidance.

Table 4. Logistic Regression Analyses of Two Models Predicting ESC Score

<table>
<thead>
<tr>
<th>Item</th>
<th>β (SE)</th>
<th>(\chi^2)</th>
<th>df</th>
<th>p</th>
<th>PPV (%)</th>
<th>NPV (%)</th>
<th>% Agreement With Full ESC</th>
</tr>
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<tbody>
<tr>
<td>Logistic Model Testing Individual Items of the ESC</td>
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<td></td>
</tr>
<tr>
<td>1. Risks</td>
<td>3.9 (0.60)</td>
<td>41.6</td>
<td>1</td>
<td>.00</td>
<td>95</td>
<td>81</td>
<td>86</td>
</tr>
<tr>
<td>2. Expect</td>
<td>5.3 (1.1)</td>
<td>23.2</td>
<td>1</td>
<td>.00</td>
<td>99</td>
<td>78</td>
<td>93</td>
</tr>
<tr>
<td>3. Withdraw</td>
<td>3.7 (1.3)</td>
<td>8.1</td>
<td>1</td>
<td>.00</td>
<td>0</td>
<td>100</td>
<td>63</td>
</tr>
<tr>
<td>4. Discomfort</td>
<td>19.6 (3827.6)</td>
<td>0.0</td>
<td>1</td>
<td>.99</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>5. Assign</td>
<td>4.2 (0.89)</td>
<td>21.4</td>
<td>1</td>
<td>.00</td>
<td>0</td>
<td>100</td>
<td>63</td>
</tr>
<tr>
<td>Logistic Model Testing Age, Gender, and Cognitive Status</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td>0.21 (0.38)</td>
<td>0.31</td>
<td>1</td>
<td>.57</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Age</td>
<td>0.01 (0.02)</td>
<td>0.02</td>
<td>1</td>
<td>.91</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>MMSE</td>
<td>2.0 (0.30)</td>
<td>49.9</td>
<td>1</td>
<td>.00</td>
<td>84</td>
<td>52</td>
<td>65</td>
</tr>
</tbody>
</table>

Notes: PPV = positive predictive value; NPV = negative predictive value; MMSE = Mini-Mental State Exam. SE = standard error. The two models are individual items of the Evaluation to Sign Consent (ESC) and demographic variables and cognitive status. The ESC score is pass or fail.

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