

University of Groningen

## The process of obtaining informed consent to research in long term care facilities (LTCFs)

Tori, Katerina; Kalligeros, Markos; Shehadeh, Fadi; Khader, Rajamohammed; Nanda, Aman; van Aalst, Robertus; Chit, Ayman; Mylonakis, Eleftherios

*Published in:*  
Medicine

*DOI:*  
[10.1097/MD.00000000000020225](https://doi.org/10.1097/MD.00000000000020225)

**IMPORTANT NOTE:** You are advised to consult the publisher's version (publisher's PDF) if you wish to cite from it. Please check the document version below.

*Document Version*  
Publisher's PDF, also known as Version of record

*Publication date:*  
2020

[Link to publication in University of Groningen/UMCG research database](#)

### *Citation for published version (APA):*

Tori, K., Kalligeros, M., Shehadeh, F., Khader, R., Nanda, A., van Aalst, R., Chit, A., & Mylonakis, E. (2020). The process of obtaining informed consent to research in long term care facilities (LTCFs): An Observational Clinical Study. *Medicine*, 99(21), e20225. [e20225].  
<https://doi.org/10.1097/MD.00000000000020225>

### **Copyright**

Other than for strictly personal use, it is not permitted to download or to forward/distribute the text or part of it without the consent of the author(s) and/or copyright holder(s), unless the work is under an open content license (like Creative Commons).

The publication may also be distributed here under the terms of Article 25fa of the Dutch Copyright Act, indicated by the "Taverne" license. More information can be found on the University of Groningen website: <https://www.rug.nl/library/open-access/self-archiving-pure/taverne-amendment>.

### **Take-down policy**

If you believe that this document breaches copyright please contact us providing details, and we will remove access to the work immediately and investigate your claim.

*Downloaded from the University of Groningen/UMCG research database (Pure): <http://www.rug.nl/research/portal>. For technical reasons the number of authors shown on this cover page is limited to 10 maximum.*

# The process of obtaining informed consent to research in long term care facilities (LTCFs)

## An Observational Clinical Study

Katerina Tori, ScB<sup>a</sup>, Markos Kalligeros, MD<sup>a</sup>, Fadi Shehadeh, MEng<sup>a</sup>, Rajamohammed Khader, MTech<sup>a</sup>, Aman Nanda, MD<sup>b</sup>, Robertus van Aalst, MSc<sup>c,d</sup>, Ayman Chit, MBiotech, PhD<sup>c,e</sup>, Eleftherios Mylonakis, MD, PhD<sup>a,\*</sup>

### Abstract

We examined the process of obtaining informed consent (IC) for clinical research purposes in long-term care facilities (LTCFs) in Rhode Island (RI), USA. We assessed factors that were associated with resident ability to consent, such as *Brief Interview for Mental Status* scores. We used a self-administered questionnaire to further understand the effect of LTCF staff evaluation of ability to consent on residents' autonomy and control over their medical decision making.

Observational clinical study

Long-term care setting.

LTCF personnel provided us with residents' names, as well as their professional assessment of resident ability to consent. We used *Brief Interview for Mental Status* (BIMS) scores to assess the cognitive capacity of all residents to assess, and compare it to the assessment provided by LTCF personnel. A logistic regression analysis was performed to determine the relationship between LTCF assessment of resident ability to consent and BIMS score or confirmed diagnosis of dementia as seen from residents' medical charts. A self-administered questionnaire was filled out by the personnel of 10 LTCFs across RI, USA.

LTCF personnel in 9 out of 10 recruited facilities reported that their assessment of resident ability to consent was based on subjective assessment of the resident as alert and oriented. There was a statistically significant relationship between the LTCF assessment of resident ability to consent and previously diagnosed dementia (OR: 0.211, 95% CI 0.107–0.415). Therefore, as BIMS scores increased, the likelihood that the resident would be deemed able to consent by LTCF personnel also increased. Furthermore, there was a statistically significant relationship between LTCF assessment of resident ability to consent and BIMS scores (OR: 1.430, 95% CI 1.274–1.605).

There is no standard on obtaining IC for research studies conducted in LTCFs. We recommend that standardizing the process of obtaining IC in LTCFs can enhance the ability to perform research with LTCF residents.

**Abbreviations:** BIMS = brief interview for mental status, CI = confidence interval, LTCF = long-term care facility, IC = informed consent, LOS = length of stay, MDS = minimum data set, OR = odds ratio.

**Keywords:** consent, dementia, long term care facility, medical decision making

Editor: Daryle Wane.

**Summary:** 9/10 LTCFs used subjective evaluation of the residents' cognition to determine ability to consent to research. We advocate for comprehensive and composite assessments of ability to consent.

The clinical study was funded by Sanofi Pasteur.

The authors have no conflicts of interest to disclose.

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Supplemental Digital Content is available for this article.

<sup>a</sup> Division of Infectious Diseases, Brown University, <sup>b</sup> Division of Geriatrics and Palliative Medicine, Warren Alpert Medical School, Providence, Rhode Island, <sup>c</sup> Regional Epidemiology and Health Economics, Sanofi Pasteur, Swiftwater, PA, <sup>d</sup> Faculty of Medical Sciences, University of Groningen, Groningen, The Netherlands, <sup>e</sup> Leslie Dan Faculty of Pharmacy, University of Toronto, Toronto, Ontario, Canada.

\* Correspondence: Eleftherios Mylonakis, Infectious Diseases Division, Warren Alpert Medical School of Brown University, Rhode Island Hospital 593 Eddy Street, POB, 3rd Floor, Suite 328/330, Providence, RI 02903 (e-mail: emylonakis@lifespan.org).

Copyright © 2020 the Author(s). Published by Wolters Kluwer Health, Inc.

This is an open access article distributed under the terms of the Creative Commons Attribution-Non Commercial License 4.0 (CCBY-NC), where it is permissible to download, share, remix, transform, and buildup the work provided it is properly cited. The work cannot be used commercially without permission from the journal.

How to cite this article: Tori K, Kalligeros M, Shehadeh F, Khader R, Nanda A, van Aalst R, Chit A, Mylonakis E. The process of obtaining informed consent to research in long term care facilities (LTCFs): an observational clinical study. *Medicine* 2020;99:21(e20225).

Received: 16 June 2019 / Received in final form: 23 March 2020 / Accepted: 7 April 2020

<http://dx.doi.org/10.1097/MD.0000000000002025>

## 1. Introduction

In the United States, the elderly population is expected to grow from 35 million in 2000 to a predicted 86 million (1 in 5) people by 2050.<sup>[1]</sup> With longer lifespans the Population Reference Bureau predicts that by 2060 there will be about 2.3 million individuals over the age of 65 residing in nursing facilities.<sup>[2]</sup> Unfortunately, despite the widespread population they service, long-term care facilities (LTCFs) have not received the level of scientific attention and study that other areas of the healthcare field have.<sup>[3]</sup>

The ethics of informed consent (IC) is a major challenge to conducting research in LTCFs. LTCF residents are considered a vulnerable population, primarily because at least 50% of them suffer from some degree of cognitive impairment.<sup>[4]</sup> Therefore, questions related to decision-making capacity are common. Mezey et al<sup>[5]</sup> and Brod et al<sup>[6]</sup> determined that moderately cognitively impaired individuals can respond to questions about end-of-life care decisions<sup>[5]</sup> and quality of life.<sup>[6]</sup> Furthermore, Buckles et al suggested that very mildly and mildly demented individuals understood the information provided to them during the consent process, whereas the involvement of a responsible caregiver was necessary for residents with moderate dementia.<sup>[7]</sup> Effectively, an individual's capacity to consent should be assessed separately for each research protocol.<sup>[8]</sup>

In the US, an individual should demonstrate four abilities to be deemed able to consent<sup>[9]</sup>:

- (1) be able to understand choices and their consequences,
- (2) be able to understand relevant information,
- (3) be able to understand associated risks and benefits, and
- (4) be able to communicate a choice.

To the best of our knowledge, there is no golden standard used to determine capacity to give IC.<sup>[10]</sup> In this study, we evaluated the LTCF personnel's assessment of resident ability to provide IC to clinical research, and studied potential limitations to resident autonomy.

## 2. Methods

### 2.1. Study design

This study is part of a larger minimally-invasive observational clinical study on the impact of vaccine-preventable infections among LTCF residents in RI, USA. Our sample included 284 long-term care residents. Upon receiving approval from the Institutional Review Board, each LTCF was contacted and given a full description of the study, along with copies of the study protocol and accompanying documents. Following a letter of cooperation, LTCFs provided a list of long-term residents, and their evaluation as consentable or non-consentable individuals. LTCF specific characteristics, including the percentage of long-term residents and Medicare rating for each facility<sup>[11]</sup> can be found in Supplemental Digital Material, Table 2, <http://links.lww.com/MD/E259>.

A self-administered questionnaire (Supplemental Digital Material, Table 1, <http://links.lww.com/MD/E258>) was given to LTCF directors of nursing and social workers, in order to explore the process of the creation of the list with long-term residents. Three researchers answered potential questions at their assigned facilities. This improved the inter-subjectivity of the results provided by different facilities. No restrictions were placed on the residents' age of eligibility. When interviews were

completed, we obtained *Brief Interview for Mental Status* scores for all 284 recruited residents included in the study. BIMS was the only consistent tool assessing cognitive capacity across all LTCFs. The BIMS assessment has been validated among nursing home residents under the minimum data set (MDS) 2.0 and 3.0 which instructed nursing home staff to administer the BIMS assessment to all their residents who could communicate in any sort of way, followed by what the MDS considers as the gold standard for assessment of cognitive function, namely the modified mini mental status (3MS) exam.<sup>[12]</sup> In our study, residents who were cognitively unable to be interviewed by the LTCF staff were not included in our analyses. BIMS scores range from 1 to 15. Scores of 1 to 7 indicate severe impairment, 8 to 12 indicate mild impairment, and 13 to 15 indicate intact cognitive abilities.<sup>[13]</sup>

### 2.2. Consent process

**2.2.1. Residents perceived by LTCF staff as consentable.** We visited residents in a private area. During this visit, we verbally reviewed all elements of the Institutional Review Board -approved consent, including the study's purpose, methods, risks, and benefits. Furthermore, we asked for permission to obtain information about their medical records through a medical records release form.

**2.2.2. Residents perceived by LTCF staff as non-consentable.** We placed telephone calls to all proxies. During this time, a researcher explained the protocol, including the study goals, methods, risks, and benefits. The researcher then met the proxy in a private setting at the facility to obtain consent.

### 2.3. Data analysis

The analyses performed aimed at describing the resident population and their cognitive status based on both BIMS scores and LTCF personnel assessment. All data were acquired from the individual nursing homes, and there were no missing data.

Mean resident age, length of stay (LOS) and BIMS scores with 95% confidence intervals were calculated for all facilities in order to examine differences among LTCFs (Tables 1 and 2). The most recent admission date was used to calculate LOS for residents who had left the LTCF for longer than 6 months and then returned. A Student's *t* test was performed to determine if there was a statistically significant difference in the mean BIMS scores of residents perceived by LTCF staff as either consentable or non-consentable.

We carried out a logistic regression analysis to examine the association between the LTCF evaluation of ability to consent and BIMS scores. Age, gender, the facility and number of years spent in the LTCF were included in the logistic regression model to account for confounding factors. Crude odds ratios did not account for confounding factors. LTCF#9 provided only consentable residents, and was not included in the logistic regression.

Finally, a logistic regression analysis was performed to examine the association between LTCF determination of ability to consent and an existing diagnosis of dementia. The regression model was adjusted for age, gender, the facility and number of years spent in the LTCF factors.

Residents who could not be interviewed by LTCF staff using the BIMS examination were not included in the logistic regression analyses. All calculations were performed using STATA 15.1 (StataCorp LLC, TX). The significance threshold was set at  $P < .05$ .

**Table 1****LTCF determination of ability to consent and average BIMS scores for residents perceived as able to consent (Consentable).**

Facility	No. of consentable residents	Mean BIMS score, range (95% CI)	Mean age (95% CI)	Mean years in LTCF (95% CI)
LTCF#1	15	13.1, 7–15 (11.7–14.5)	80.3 (73.4–87.1)	1.7 (0.9–2.5)
LTCF#2	31	14.2, 8–15 (13.5–14.8)	77.7 (74.2–81.2)	2.3 (1.6–3.1)
LTCF#3*	1	10.0	80	2.11
LTCF#4	7	11.7, 6–15 (8.6–14.8)	91.1 (85.4–96.9)	4.3 (0.6–8.1)
LTCF#5	7	13.3, 5–15 (10.5–16.0)	82.0 (75.2–88.8)	3.6 (2.1–5.2)
LTCF#6	13	12.2, 4–15 (10.4–14.1)	81.6 (74.2–89.1)	2.4 (1.4–3.5)
LTCF#7	5	13.2, 8–15 (10.5–15.9)	70.6 (60.3–80.9)	2.8 (1.3–4.2)
LTCF#8†	4	15	72.8 (61.2–84.3)	4.9 (2.3–7.5)
LTCF#9‡	16	14.8, 4–15 (14.5–15.0)	74.8 (70.2–79.3)	1.8 (1.0–2.6)
LTCF#10	14	14.8, 14–15 (14.6–15.0)	85.0 (79.4–90.6)	2.7 (1.2–4.2)

CI = confidence interval, LTCF = long-term care facility, BIMS = brief interview for mental status.

\* In LTCF#3 there was only one resident able to consent.

† LTCF#8 only provided us with residents with a BIMS score of 15.

### 3. Results

#### 3.1. Resident characteristics

Our sample included 284 residents, 113 were perceived as able to consent by LTCF personnel, and 171 were perceived as unable to consent. 72.5% were women, which is in accordance with the results of the 2004 National Nursing Home Survey.<sup>[14]</sup> The mean age was 83.4 years, and 98.6% were English speaking. The mean LOS in the LTCF was 2.8 years. BIMS scores were available for 232 residents, because 52 were cognitively unable to complete the BIMS test. Of the residents with BIMS scores, 121 were cognitively intact, 56 were mildly impaired, and 55 severely impaired. Tables 1 and 2 summarize all demographic data for the population we studied.

#### 3.2. LTCF determination of resident ability to consent

We received lists from 10 LTCFs. Despite all 10 facilities reported use of BIMS to assess resident cognitive capacity as part of the federally mandated minimum data set (MDS) for LTCFs, 9 out of 10 facilities indicated that the BIMS score was based on subjective knowledge and interaction with the resident. LTCF#1 solely used BIMS scores to determine resident ability to consent.

#### 3.3. Residents perceived as able to consent by LTCF staff

Among residents perceived as consentable by LTCF staff, BIMS scores were on average over 13 in 7 facilities (Table 1). Thus, in

these facilities, on average cognitively intact residents were considered consentable. However, the range indicates that some residents with a BIMS score of mild or severe impairment were also considered consentable. In 3 other facilities, residents' BIMS scores ranged from 10.0 to 12.23. In these facilities, on average mildly impaired individuals were perceived as able to consent, as well as some severely impaired and cognitively intact individuals.

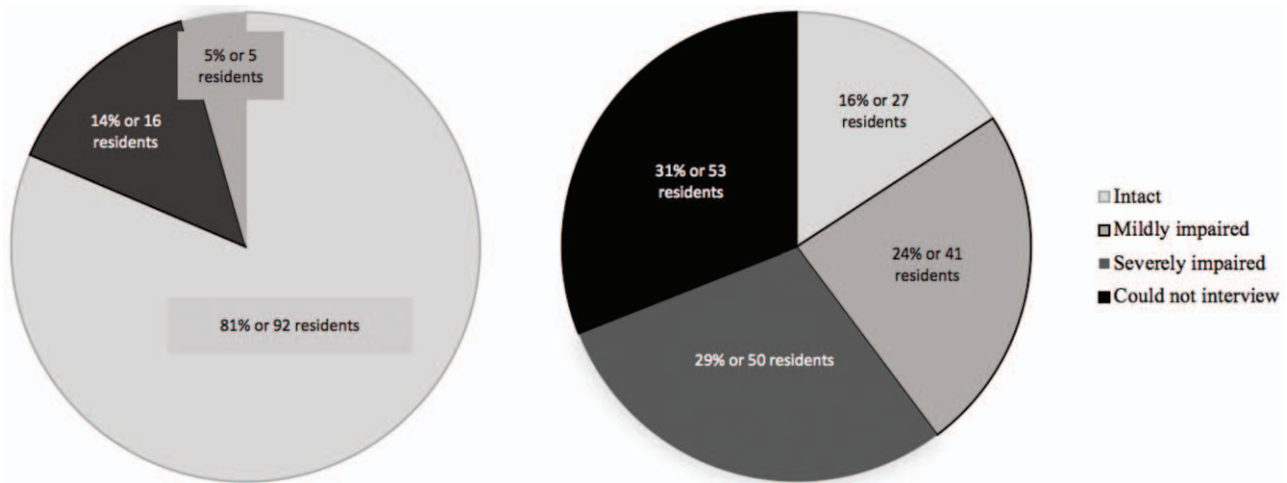
Interestingly, 2 LTCFs (LTCF#1, LTCF#4) elected to not assess resident ability to consent without the family's permission. Therefore, all residents' families were called asked if they wanted to meet with us to provide consent. Some families wanted to meet with us first, whereas others instructed the LTCF staff to assess resident ability to consent. When families met with us some allowed the resident to consent, but some did not. Thus, individuals able to consent were not provided the autonomy to do so. BIMS score ranges (Table 1) indicated that on average cognitively intact residents ( $BIMS \geq 13$ ) were perceived as consentable in LTCF#1, but also some mildly and severely impaired individuals. Moderately ( $8 \leq BIMS \leq 12$ ) and severely ( $1 \leq BIMS \leq 7$ ) impaired residents were perceived as able to consent by LTCF staff in LTCF#4. Figure 1 further illustrates these points, where 14% mildly and 5% severely impaired individuals were perceived as able to consent. These observations are in agreement with the responses LTCF personnel provided on the self-administered questionnaire.

**Table 2****LTCF determination of ability to consent and average BIMS scores for residents perceived as unable to consent (Non-consentable).**

Facility	No. of non-consentable residents	Mean BIMS score, Range (95% CI)	Mean age (95% CI)	Mean years in LTCF (95% CI)
LTCF#1	27	10.6, 3–15 (8.8–12.3)	86.3 (81.5–91.1)	2.7 (1.4–4.0)
LTCF#2	19	10.9, 8–15 (9.1–12.7)	83.0 (76.1–89.9)	3.2 (1.4–4.9)
LTCF#3	13	7.6, 2–13 (3.7–11.5)	92.6 (85.8–99.4)	3.0 (1.2–4.7)
LTCF#4	7	8.0, 2–14 (4.1–11.9)	91.4 (86.5–96.3)	1.5 (0.6–2.4)
LTCF#5	22	6.6, 2–14 (4.6–8.6)	91.7 (88.3–95.2)	3.8 (1.6–6.1)
LTCF#6	15	7.8, 3–15 (5.3–10.3)	83.5 (77.8–89.2)	3.0 (2.1–3.8)
LTCF#7	12	9.9, 3–15 (6.1–13.6)	71.1 (66.0–76.2)	5.5 (3.6–7.5)
LTCF#8	22	7.1, 3–14 (5.1–9.0)	86.2 (80.4–92.0)	1.9 (1.0–2.9)
LTCF#9*				
LTCF#10	34	8.1, 2–15 8.1 (6.3–9.9)	90.5 (88.3–92.7)	2.9 (2.1–3.7)

CI = confidence interval, LTCF = long-term care facility, BIMS = brief interview for mental status.

\* LTCF#9 only provided us with residents able to consent.



**Figure 1.** BIMS score distributions for residents perceived as consentable (left image) or non-consentable residents (right image) by LTCF personnel. Intact:  $BIMS \geq 13$ ; Mildly impaired:  $8 \leq BIMS \leq 12$ ; Severely impaired:  $1 \leq BIMS \leq 7$ .

### 3.4. Residents perceived as unable to consent by LTCF staff

Among residents perceived as non-consentable by LTCF staff, residents who because of their severely impaired cognition could not be interviewed (31%) were not included in the statistical analyses.

BIMS scores ranged from 8.0 to 12.23 in 5 facilities, with a lower and upper limit of 2 and 15 respectively, for those who could be interviewed. Thus, on average, residents who based on their BIMS score were mildly impaired (24%) were perceived as unable to consent. Furthermore, some intact (16%) and severely impaired residents (29%) were perceived as unable to consent (Fig. 1). Supplemental Digital Material, Table 3, <http://links.lww.com/MD/E260> details the reasons why 16% of residents with an intact BIMS score were perceived as unable to consent. In the remaining 5 facilities, BIMS scores ranged from 6.56 to 7.83, with a lower and upper limit of 2 and 14 respectively. Essentially, on average, severely impaired individuals were considered unable to consent by LTCF staff. However, some mildly impaired and cognitively intact individuals were also perceived as unable to consent.

### 3.5. Association of LTCF determination of ability to consent and BIMS score

A Student's *t* test showed that there was a statistically significant difference between the mean BIMS scores of residents perceived as consentable and non-consentable by LTCF staff ( $P < .001$ ). Consentable subjects had a mean BIMS score of 13.7 (95% CI, 13.2–14.2), compared to 8.4 (95% CI, 7.7–9.2) for non-consentable residents. We stratified the subjects by facility and found no statistically significant differences between mean BIMS scores of residents perceived by LTCF staff as consentable or non-consentable among facilities.

The logistic regression analysis showed that consentable residents were more likely to have higher BIMS scores compared to non-consentable residents (OR: 1.43, 95% CI, 1.27–1.61) (Table 3). For each unit increase in BIMS scores the odds of being consentable increased by a factor of 1.43, meaning that the

resident was 43% more likely to be considered consentable by the LTCF. There was no statistically significant finding between age, sex, the facility or the length of stay in the LTCF, and LTC determination of ability to consent (Table 3). When no confounders were considered, BIMS scores remained significantly positively associated with LTCF assessment of resident ability to consent (OR: 1.48, 95% CI, 1.34–1.64) (Table 3).

### 3.6. Association of LTCF determination of ability to consent and dementia

A logistic regression analysis showed that a previous diagnosis of dementia was significantly negatively associated with LTCF personnel assessment of resident ability to consent (OR: 0.21, 95% CI, 0.11–0.42) (Table 4). Thus, residents without dementia

**Table 3**  
Association between LTCF assessment of resident ability to consent and BIMS scores, with and without confounders.

	Adjusted odds ratio	95% CI
BIMS Score	1.430	1.274–1.605
Age	0.969	0.935–1.003
Sex	0.701	0.300–1.636
LTCF#1	0.913	0.234–3.564
LTCF#2	2.480	0.631–9.745
LTCF#3	0.411	0.033–5.134
LTCF#4	5.488	0.830–36.296
LTCF#5	Reference	
LTCF#6	2.674	0.590–12.130
LTCF#7	0.630	0.099–4.001
LTCF#8	0.514	0.087–3.029
LTCF#9*		
LTCF#10	0.862	0.216–3.442
Years in LTCF	0.948	0.825–1.089
	Crude odds ratio	95% CI
BIMS Score	1.483	1.338–1.644

CI = confidence interval, BIMS = brief interview for mental status examination, LTCF = long-term care facility.

\* There were no subjects perceived by LTCF staff as unable to consent.

**Table 4**  
**Association between LTCF assessment of resident ability to consent and dementia, with and without confounders.**

	Adjusted odds ratio	95% CI
Dementia	0.211	0.107–0.415
Age	0.956	0.925–0.987
Sex	0.576	0.266–1.245
LTCF#1	1.461	0.426–5.015
LTCF#2	5.137	1.481–17.818
LTCF#3	1.162	0.107–12.670
LTCF#4	4.925	0.990–24.511
LTCF#5	Reference	
LTCF#6	2.357	0.630–8.821
LTCF#7	0.891	0.162–4.908
LTCF#8	0.549	0.112–2.684
LTCF#9*		
LTCF#10	1.675	0.497–5.642
Years in LTCF	0.973	0.858–1.104
	Crude odds ratio	95% CI
Dementia	0.161	0.0899–0.287

CI = confidence interval, LTCF = long-term care facility.

\* There were only residents perceived by LTCF staff as able to consent.

were 78.9% more likely to be perceived as consentable by LTCF staff. Furthermore, age had a negative and statistically significant association with LTCF assessment of ability to consent (OR: 0.96, 95% CI, 0.93–0.99). Finally, there was a positive and statistically significant association between residents with dementia who live in LTCF#2 and LTCF assessment of ability to consent (OR: 5.14, 95% CI, 1.48–17.82).

### 3.7. Self-administered questionnaire

The LTCF staff reported that cognitive impairment and family involvement are challenges they face when trying to provide residents with more control over their medical decision making. Furthermore, lack of trust, misinformation and fear of experimentation affect a resident's desire to consent to research. When asked how one can help residents have a voice for themselves, most LTCFs stressed the need to offer more ability to make decisions. However, they were unable to provide concrete ways to achieve this objective. All LTCFs reported fulfillment of state department requirements, as the main reason for participating in a clinical study. Finally, helping residents advocate for themselves was consistently a major challenge. The questionnaire is provided in the Supplemental Digital Material, Table 1, <http://links.lww.com/MD/E258>.

## 4. Discussion

In the present study, we found that there was a statistically significant relationship between LTCF assessment of resident ability to consent and BIMS scores, as well as with a previous diagnosis of dementia. Therefore, despite 9 out of 10 LTCFs using subjective means to assess residents' cognitive abilities, their "consentability" assessment was associated with BIMS scores (aOR: 1.43, 95% CI, 1.27–1.61). This result of the regression effectively allows us to suggest that the assessment was accurate overall, where the higher the BIMS score, the more likely the LTCFs were to assess the resident as able to consent. Furthermore, we found a statistically significant relationship

between diagnosed dementia and LTCF assessment of resident ability to consent. There was no statistical difference between the recruited LTCFs. However, among residents perceived as unable to consent by LTCF personnel, 17% were cognitively intact based on their BIMS scores.

Ability to consent is a key tenet of the ethical conduct of human research,<sup>[15]</sup> and spans both ethical and legal dimensions.<sup>[16]</sup> Cognitive capacity is the core requirement for IC; that is, whether an individual can provide consent, or whether consent must be obtained from a proxy. IC is particularly complex for individuals who are elderly, live in a nursing facility, or suffer from dementia.<sup>[4,17]</sup> Historically, LTCFs have defaulted to seeking IC from a proxy, especially in cases of patients with dementia.<sup>[18–20]</sup> This presumption takes away a resident's voice, therefore disregarding their autonomy and privacy.<sup>[21]</sup> Moreover, involvement of a proxy assumes ability on the part of the proxy to accurately reflect the resident's wishes.<sup>[22]</sup> As detailed above, LTCF#1 and LTCF#4 decided to consult with proxies before allowing us to approach the residents or their responsible parties. Interestingly, both of these facilities assessed cognitively intact individuals as unable to consent. This could indicate that the decision by LTCF personnel to consult proxies despite the residents' cognitive ability to consent, took away their right to choose for themselves.

To date, there is no standard used to determine capacity to give IC.<sup>[10]</sup> Additionally, there is no standard for the process of IC that LTCFs can follow when determining participation in research. Limited guidance exists for projects including individuals with dementia. The US National Institutes of Health produced a detailed document in 2009 describing various ways that would be used to determine capacity to consent.<sup>[23]</sup> Although, they did not recommend one particular technique, they did point out that capacity should be assessed for a specific research study and not broadly.<sup>[23]</sup> Thus, it is encouraging that our data showed that LTCF staff did not perceive residents as unable to consent on the basis of a diagnosis of dementia.

Due to its broad usage throughout the recruited LTCFs, we chose the *Brief Interview for Mental Status* (BIMS) examination as an assessment of cognitive function. BIMS is a rapidly and widely administered instrument used as part of the MDS—a federally mandated process that measures the health status of LTCF residents.<sup>[24]</sup> A recent study showed that BIMS can predict cognitive diagnoses, however, the *Brief Cognitive Assessment Tool-Short Form* (BCAT-SF) is more sensitive and able to differentiate among all cognitive levels.<sup>[25]</sup> The *Mini Mental Status Examination* (MMSE) is a "practical method" to assess cognition.<sup>[26]</sup> However, MMSE also has a low sensitivity and specificity in terms of capacity.<sup>[27]</sup> Finally, the *Aid to Capacity Evaluation* (ACE) is suggested as the best available instrument to assist clinicians in assessing medical decision-making capacity.<sup>[27]</sup> The ACE is the only instrument accompanied by training materials.<sup>[27]</sup> We do not recommend the BIMS examination as the standard to assessing capacity to IC.

Standardizing the process of IC in LTCFs can enhance the ability to perform research with LTCF subjects. The implementation of a commonly accepted, objective and easy to use assessment, such as the BIMS examination, can be a step in the right direction. Especially for minimally invasive studies, such as the one described here, being cognitively intact (i.e., BIMS $\geq$ 13) should afford residents the ability to decide if they would like to participate in a research study. However, the limitations of the BIMS instrument, and current research suggesting that cognitive

testing alone is insufficient to assess the presence of capacity,<sup>[28]</sup> tell us that new and more holistic approaches to assessing individuals' consent to participate in research are required.

Researchers in future studies could use more composite cognitive assessment tools to assess resident ability to consent. Warner et al establish the use of 4 key elements when assessing capacity to consent —providing salient and comprehensible information, allowing time to understand and retain the information, testing retention and belief, and assessing ability to weight the information.<sup>[28]</sup> Approaching all residents without having been influenced by the nursing staff' judgment of residents' cognitive state, and assessing the aforementioned elements will allow for a more objective assessment of consent. All the while increasing resident autonomy to providing consent in different circumstances.

This study has some notable limitations. First, the study was limited to residents of only 10 facilities in RI, USA, so our sample might not be representative of different populations across the state or the nation. Second, the questionnaire used was not standardized and currently in broad use, which meant providers were not familiar with it, and might have had difficulty responding to all questions. Third, we relied on the subjective cognitive assessment we were provided by the LTCF staff, and did not administer additional tests to assess the ability to consent. Therefore, we did not adhere to the "situational"<sup>[8]</sup> dimension of consent. LTCF staff were asked to provide lists qualifying residents as able or unable to consent, but we did not visit the residents to determine whether, despite potential cognitive incapacities they might have been able to respond to this particular project. Lastly, our study followed an observational design, and thus we cannot be certain that we have accounted for all potential confounding factors.

## 5. Conclusions and implications

As the population of adults living in LTCFs is rising,<sup>[2]</sup> quality of care and research should be top priorities.<sup>[29,30]</sup> An evidence-based determination of the challenges (infections, living conditions, medication over-prescription, etc.) that residents face, will facilitate the advancement of care in LTCFs and other long-term care settings. Autonomy to consent might be another significant challenge that LTCF residents face. Therefore, the present study hopes to provide insight into the process of IC and the associated hardships, effectively providing directives for future research in similar settings to further resident autonomy and quality of care.

## Acknowledgments

The authors would like to thank the facilities, staff, residents and families who volunteered their time to participate in this research.

## Author contributions

**Conceptualization:** Eleftherios Mylonakis.

**Data curation:** Katerina Tori, Markos Kalligeros, Fadi Shehadeh, Rajamohammed Khader, Aman Nanda, Robertus van Aalst, Ayman Chit, Eleftherios Mylonakis.

**Formal analysis:** Katerina Tori, Markos Kalligeros, Fadi Shehadeh, Rajamohammed Khader, Aman Nanda, Robertus van Aalst, Ayman Chit, Eleftherios Mylonakis.

**Funding acquisition:** Robertus van Aalst, Ayman Chit, Eleftherios Mylonakis.

**Project administration:** Eleftherios Mylonakis.

**Supervision:** Eleftherios Mylonakis.

**Validation:** Eleftherios Mylonakis.

**Writing – original draft:** Katerina Tori, Markos Kalligeros, Fadi Shehadeh, Rajamohammed Khader, Aman Nanda, Robertus van Aalst, Ayman Chit, Eleftherios Mylonakis.

**Writing – review & editing:** Katerina Tori, Markos Kalligeros, Fadi Shehadeh, Rajamohammed Khader, Aman Nanda, Robertus van Aalst, Ayman Chit, Eleftherios Mylonakis.

## References

- [1] Smith SK, Rayer S, Smith EA. Aging and disability: implications for the housing industry and housing policy in the United States. *J Am Plan Assoc* 2008;74:289–306.
- [2] Mark Mather LAJ, Kelvin MP. Aging in the United States. Population Reference Bureau 2015;70:
- [3] Resnick B, Gruber-Baldini AL, Pretzer-Aboff I, et al. Reliability and validity of the evaluation to sign consent measure. *Gerontologist* 2007; 47:69–77.
- [4] Gruber-Baldini AL, Zimmerman SI, Mortimore E, et al. The validity of the minimum data set in measuring the cognitive impairment of persons admitted to nursing homes. *J Am Geriatr Soc* 2000;48:1601–6.
- [5] Mezey M, Teresi J, Ramsey G, et al. Decision-making capacity to execute a health care proxy: development and testing of guidelines. *J Am Geriatr Soc* 2000;48:179–87.
- [6] Brod M, Stewart AL, Sands L, et al. Conceptualization and measurement of quality of life in dementia: the dementia quality of life instrument (DQoL). *Gerontologist* 1999;39:25–35.
- [7] Buckles VD, Powlishta KK, Palmer JL, et al. Understanding of informed consent by demented individuals. *Neurology* 2003;61:1662–6.
- [8] Informed consent for research on human subjects with dementia. AGS Ethics Committee. American Geriatrics Society. *J Am Geriatr Soc* 1998;46:1308–10.
- [9] Appelbaum PS, Grisso T. The MacArthur Treatment Competence Study. I: Mental illness and competence to consent to treatment. *Law Hum Behav* 1995;19:105–26.
- [10] Thorogood A, Maki-Petaja-Leinonen A, Brodaty H, et al. Consent recommendations for research and international data sharing involving persons with dementia. *Alzheimers Dement* 2018;14:1334–43.
- [11] Ponraj M, Dubashi B, Harish BH, et al. Cefepime vs. cefoperazone/sulbactam in combination with amikacin as empirical antibiotic therapy in febrile neutropenia. *Support Care Cancer* 2018; <https://www.medicare.gov/nursinghomecompare/search.html?> Accessed January 23 2019
- [12] 2008;Saliba D, Buchanan J. Development and Validation of a Revised Nursing Home Assessment Tool: MDS 3. 0.
- [13] Thomas KS, Dosa D, Wysocki A, et al. The minimum data set 3.0 cognitive function scale. *Med Care* 2017;55:e68–72.
- [14] Kuderer NM, Dale DC, Crawford J, et al. Mortality, morbidity, and cost associated with febrile neutropenia in adult cancer patients. *Cancer* 2006;106:2258–66.
- [15] Ioannidis JP. Informed consent, big data, and the oxymoron of research that is not research. *Am J Bioeth* 2013;13:40–2.
- [16] Freifeld AG, Bow EJ, Sepkowitz KA, et al. Clinical practice guideline for the use of antimicrobial agents in neutropenic patients with cancer: 2010 update by the infectious diseases society of America. *Clin Infect Dis* 2011;52:e56–93.
- [17] Hougham GW. Waste not, want not: cognitive impairment should not preclude research participation. *Am J Bioeth* 2005;5:36–7. author reply W15–38.
- [18] Hubbard G, Downs MG, Tester S. Including older people with dementia in research: challenges and strategies. *Aging Ment Health* 2003;7:351–62.
- [19] Jongsma KR, van de Vathorst S. Beyond competence: advance directives in dementia research. *Monash Bioeth Rev* 2015;33:167–80.
- [20] Kim SY, Kim HM, Ryan KA, et al. How important is 'accuracy' of surrogate decision-making for research participation? *PLoS One* 2013;8: e54790.
- [21] Beattie E, O'Reilly M, Fetherstonhaugh D, et al. Supporting autonomy of nursing home residents with dementia in the informed consent process. *Dementia (London)* 2019;18:2821–35.

- [22] Warren JW, Sobal J, Tenney JH, et al. Informed consent by proxy. An issue in research with elderly patients. *N Engl J Med* 1986;315:1124–8.
- [23] Nakane T, Tamura K, Hino M, et al. Cefozopran, meropenem, or imipenem-cilastatin compared with cefepime as empirical therapy in febrile neutropenic adult patients: a multicenter prospective randomized trial. *J Infect Chemother* 2015;21:16–22.
- [24] Saliba D, Buchanan J. Development and Validation of a Revised Nursing Home Assessment Tool: MDS 3.0. 2008.
- [25] Mace RA, Mansbach WE, Clark KM. Rapid cognitive assessment of nursing home residents: a comparison of the brief interview for Mental status (BIMS) and brief cognitive assessment tool-short form (BCAT-SF). *Res Gerontol Nurs* 2016;9:35–44.
- [26] Folstein MF, Folstein SE, McHugh PR. “Mini-mental state”. A practical method for grading the cognitive state of patients for the clinician. *J Psychiatr Res* 1975;12:189–98.
- [27] Sessums LL, Zembrzuska H, Jackson JL. Does this patient have medical decision-making capacity? *JAMA* 2011;306:420–7.
- [28] Warner J, McCarney R, Griffin M, et al. Participation in dementia research: rates and correlates of capacity to give informed consent. *J Med Ethics* 2008;34:167–70.
- [29] Maas ML, Kelley LS, Park M, et al. Issues in conducting research in nursing homes. *West J Nurs Res* 2002;24:373–89.
- [30] Dellefield ME. The relationship between nurse staffing in nursing homes and quality indicators. *J Gerontol Nurs* 2000;26:14–28.