

Fact Box decision support tools reduce decisional conflict about antibiotics for pneumonia and artificial hydration in advanced dementia: a randomized controlled trial

Journal Article**Author(s):**

Loizeau, Andrea; Theill, Nathan; Cohen, Simon M.; Eicher, Stefanie; Mitchell, Susan L.; Meier, Silvio; McDowell, Michelle; Martin, Mike; Riese, Florian

Publication date:

2019-01

Permanent link:

<https://doi.org/10.3929/ethz-b-000394166>

Rights / license:

[In Copyright - Non-Commercial Use Permitted](#)

Originally published in:

Age and Ageing 48(1), <https://doi.org/10.1093/ageing/afy149>

Fact Box decision support tools reduce decisional conflict about antibiotics for pneumonia and artificial hydration in advanced dementia: a randomized controlled trial

ANDREA J. LOIZEAU^{1,2,3}, NATHAN THEILL^{1,2,4}, SIMON M. COHEN³, STEFANIE EICHER^{1,2}, SUSAN L. MITCHELL^{3,5}, SILVIO MEIER^{2,6}, MICHELLE McDOWELL⁷, MIKE MARTIN^{1,2,6}, FLORIAN RIESE^{1,4}

¹University Research Priority Program 'Dynamics of Healthy Aging', University of Zurich, 8006 Zurich, Switzerland

²Center for Gerontology, University of Zurich, 8032 Zurich, Switzerland

³Hebrew SeniorLife Institute for Aging Research, Roslindale, MA 02131, USA

⁴Division of Psychiatry Research and Psychogeriatric Medicine, University of Zurich, 8032 Zurich, Switzerland

⁵Department of Medicine, Beth Israel Deaconess Medical Center, Boston, MA 02215, USA

⁶Department of Psychology, University of Zurich, 8006 Zurich, Switzerland

⁷Harding Center for Risk Literacy, Max Planck Institute for Human Development, 14195 Berlin, Germany

Address correspondence to: Andrea Jutta Loizeau, PhD, Hebrew SeniorLife Institute for Aging Research, 1200 Centre Street, Roslindale, MA 02131, USA. Tel: +1 617-971-5345, Email: andrealoizeau@hsl.harvard.edu

Abstract

Background: fact Boxes are decision support tools that can inform about treatment effects.

Objectives: to test whether Fact Box decision support tools impacted decisional conflict, knowledge and preferences about the use of antibiotics and artificial hydration in advanced dementia.

Design: randomized controlled trial.

Setting: Swiss-German region of Switzerland.

Subjects: two hundred thirty-two participants (64 physicians, 100 relatives of dementia patients, 68 professional guardians) randomly allocated to intervention ($N = 114$) or control ($N = 118$).

Intervention: two-page Fact Box decision support tools on antibiotics for pneumonia and artificial hydration in advanced dementia (at 1-month).

Methods: participants were mailed questionnaires at baseline and one month later that asked questions about treatments based on hypothetical scenarios. The primary outcome was change in decisional conflict (DCS-D; range $0 < 100$) about treatment decisions. Secondary outcomes included knowledge about treatments (range $0 < 7$) and preferences to forego treatments.

Results: participants were: mean age, 55.6 years; female, 62.8%. Relative to control participants, intervention participants experienced less decisional conflict about using antibiotics (unstandardized beta (b) = -8.35 , 95% Confidence Interval (CI), -12.43 , -4.28) and artificial hydration ($b = -6.02$, 95% CI, -9.84 , -2.20) at 1-month compared to baseline. Intervention participants displayed greater knowledge about the use of antibiotics ($b = 2.24$, 95% CI, 1.79 , 2.68) and artificial hydration ($b = 3.01$, 95% CI, 2.53 , 3.49), and were significantly more likely to prefer to forego antibiotics (odds ratio, 2.29 , 95% CI, 1.08 , 4.84) but not artificial hydration.

Conclusions: fact Box decision support tools reduced decisional conflict, increased knowledge and promoted preferences to forego antibiotics in advanced dementia among various decision-makers.

Trial registration: FORSbase (12091).

Keywords: dementia, decision-making, decision aid, palliative care, risk communication

Introduction

Dementia is a clinical syndrome that afflicts more than 50 million people worldwide [1]. In advanced dementia, patients have profound cognitive and functional deficits and frequently experience complications such as repeated pneumonia episodes and poor fluid intake [2, 3]. Consequently, patients commonly receive antibiotics and artificial hydration, but these interventions can be burdensome and have questionable benefit in the last months of life [2, 4–8].

The majority of surrogate decision-makers for advanced dementia patients are family members. These family members report lack of adequate decision support from health care providers [9, 10], which may lead to uninformed treatment decisions that do not align with goals of care [2, 4, 11]. Prior research shows that when families receive provider counseling, advanced dementia patients are less likely to undergo burdensome interventions in their last months of life [2]. In the absence of relatives, treatment decisions are made by professional guardians, but data on their experience making choices about end-of-life care is lacking.

Decision support tools improve medical decision-making by improving knowledge and reducing decisional conflict [12–15]. The few decision support tools designed specifically for proxies of patients with advanced dementia promote preferences for more comfort-focused care [14–18]. A prior randomized controlled trial (RCT) showed that a 20-min, paper-print decision support tool about feeding options in advanced dementia reduced surrogates' decisional conflict, improved their knowledge, fostered communication with providers and resulted in residents receiving increased eating assistance [15]. While most of these tools have been found to be effective, they are tailored to only a single group of decision makers [12–18]. In contrast, Fact Boxes are short, inexpensive, paper-based decision support tools that are tailored for a variety of decision-makers. Using simple, understandable language, they present balanced information on the benefits and harms of receiving versus not receiving a treatment [19, 20].

As part of the DEMentia FACT box (DEMFACT) study, we have developed the first two Fact Boxes in advanced dementia for decisions related to the use of (1) antibiotics for pneumonia and (2) artificial hydration [21]. The first Fact Box on antibiotics is a two-page, pocket-sized brochure that presents the typical features of pneumonia, the benefits and harms of using antibiotics and alternative treatment options. The second Fact Box on artificial hydration is a similar format and describes the administration, benefits, harms and alternatives to artificial hydration for suspected dehydration or reduced oral intake. The final versions are shown in Appendices 1 and 2 in Supplementary data, available in *Age and Ageing* online.

This report presents the findings of a RCT to determine the impact of our two newly developed Fact Boxes on the decisional conflict of physicians, relatives of dementia patients and professional guardians in decisions related to antibiotics for pneumonia and artificial hydration in advanced dementia.

The trial was conducted in the Swiss-German region of Switzerland. Physicians, relatives of dementia patients and professional guardians were randomized to either receive (intervention) or not receive (control) the Fact Boxes. All participants were asked to make treatment decisions about antibiotics and artificial hydration for advanced dementia patients based on hypothetical scenarios. The primary outcome was decisional conflict about treatment decisions. Secondary outcomes included knowledge about treatments, and preferences to forego antibiotics and artificial hydration.

Methods

Design

DEMFACT was a RCT conducted in the Swiss-German region of Switzerland. Participant recruitment began in April, 2016 and data collection was completed in October, 2016. The ethics commission of the canton of Zurich approved the study (KEK-ZH-No. 2015-0626). All participants provided written informed consent.

Recruitment and randomization

To understand the impact of the DEMFACT intervention on various decision-makers, participants included physicians, relatives of dementia patients and professional guardians who were potentially responsible for the care of advanced dementia patients. Physicians were identified from the mailing lists of the Swiss Association for Palliative Medicine, Care and Support, and the Swiss Geriatric Medicine Society. Relatives of dementia patients were identified through the Alzheimer Association of the canton of Zurich. Professional guardians were identified from the Swiss Association of Professional Guardians mailing list. To solicit participation, all physicians and professional guardians on the aforementioned mailing lists were sent emails in April and May of 2016, while all members of the Alzheimer Association were mailed letters in April of 2016. The emails and letters included instructions on how to contact our team if the recipient wished to participate. Participants had to be proficient in German to enroll. Individuals opting to enroll were randomly assigned by an independent statistician to either the intervention or control arm using a computer generated-randomization list with a 1:1 allocation ratio. Randomization was stratified by participant subgroups (i.e. physicians, relatives and professional guardians). Once randomized, participants received information about their arm assignment by mail and were asked to return a signed consent form to the research team.

Intervention

The intervention consisted of two Fact Box decision support tools for advanced dementia: one for decisions about antibiotic use and another for artificial hydration use [21]. The structure of these tools were based on guidelines for developing Fact Boxes and incorporated guidelines from the

International Patient Decision Aid Standards [19, 20, 22]. Their content was selected based on literature reviews conducted by two independent reviewers (A.J.L. and S.M.) on the use of antibiotics and artificial hydration in advanced dementia [6–8, 23]. Following an iterative process, the drafts of the tools were then reviewed by the head of a dementia ward (F.R.), two specialists on risk communication (M.Mc. and colleague) and eight experts on aging research (N.T., S.E., M.Ma. and colleagues).

Data collection and elements

Data collection was procedurally identical across participant subgroups, unless otherwise stated. Data were collected using two similar written questionnaires (sent and returned by mail; ~60 min to complete) completed by participants at the time of initial recruitment and 1-month follow-up.

Participants in the intervention arm were mailed the Fact Boxes along with the 1-month follow-up questionnaire. Participants in the control arm did not receive any additional information along with the 1-month follow-up questionnaire.

The baseline and follow-up questionnaires first described two hypothetical scenarios (same scenarios at each time period). One scenario presented an advanced dementia patient with pneumonia based on a case by Mitchell *et al.* (2015) [24]. The second scenario consisted of an advanced dementia patient with insufficient fluid intake based on a case by Garbiel and Tschanz (2015) [25]. The scenarios are shown in Appendices 3 and 4 in Supplementary data, available in *Age and Ageing* online. After reading each scenario, participants were subsequently asked the same series of questions pertaining to the use of antibiotics or artificial hydration. Comfort with decision-making was assessed using a validated German version of the Decisional Conflict Scale (DCS-D; 5-point Likert scale of 16 items; range 0–100, higher scores indicate greater conflict) [26, 27]. Participants' knowledge was ascertained using 7-item true-false questions specific to each treatment (scored, 1 = true, 0 = false/do not know; range 0–7, higher scores indicate greater knowledge). (The questions are shown in Appendices 5 and 6 in Supplementary data, available in *Age and Ageing* online). Preferences to use antibiotics and artificial hydration were measured using single questions with response options; 'use', 'forego' or 'undecided'.

Other participant data collected only at baseline included: demographics (age, gender and religion (Protestant, Catholic, no religion and other)), the educational level of relatives of dementia patients (\geq high school versus other), and whether participants had previously made a decision about the use of antibiotics and/or artificial hydration for a person with dementia. Professional guardians reported whether they had previously served as a legal guardian for a person with dementia.

In the intervention arm only, participants were asked to rate the helpfulness of the Fact Boxes ('helpful', 'somewhat helpful', 'neither helpful nor unhelpful', 'somewhat unhelpful' and 'unhelpful'); appropriateness of both the content and layout ('very good', 'good', 'fair', 'bad' and 'very bad')

and amount of information ('too much', 'too little' and 'exactly right'). The physicians were asked if they would feel comfortable using Fact Boxes while communicating with patients/decision-makers ('agree', 'somewhat agree', 'neither agree nor disagree', 'somewhat disagree' and 'disagree').

Statistical analysis

The trial's primary outcome was the reduction in DCS-D scores for decisions on the use of antibiotics and artificial hydration. Secondary outcomes included knowledge about each treatment, and preferences to forego the treatments. Analyses were performed using R Version 3.3.2 [28]. Means with standard deviations (SDs) and frequencies described continuous and categorical variables, respectively. Outcomes were compared between trial arms at baseline using independent *t*-tests for continuous variables and chi-squared tests for categorical variables.

Similar approaches were used to analyze outcomes for decisions related to antibiotic and artificial hydration use. Linear mixed-effects models (lme4 package) were used to examine the outcomes of DCS-D and knowledge. To capture changes between the 1-month follow-up and baseline measures in the intervention relative to the control arm, these models included a term specifying the interaction between trial arms (intervention versus control) and assessments (one-month follow-up versus baseline). Random effects were used to account for repeated measurements among individuals. Unstandardized beta (*b*) and 95% confidence intervals (CIs) were computed. Logistic regression models compared changes in treatment preferences ('forego' versus 'use' or 'undecided') between the 1-month follow-up and baseline in the intervention relative to the control arm. Odds ratios (ORs) and 95% CIs were computed. Models were generated for all participants and also stratified by participant subgroups.

A minimum sample size of 198 was calculated to provide at least 80% power to detect an effect of 0.1 between trial arms for the primary outcome. The sample size calculation assumed two repeated measurements and a 5% type I error rate. A conservative effect size was selected because the impact of decision aids on decisional conflict is highly variable [12, 13, 15].

Results

Enrollment and participant characteristics

Of the 3860 individuals approached for participation, 254 (6.6%) contacted the research team indicating their willingness to participate, and all were eligible for recruitment (the CONSORT flow diagram of participant subgroups is shown in Appendix 7 in Supplementary data, available in *Age and Ageing* online). During the course of the study, fifteen participants (intervention, *N* = 10; control, *N* = 5) stopped responding to emails and/or phone calls, and seven participants withdrew (intervention, *N* = 4; control, *N* = 3). The final analytic sample completing both baseline and follow-up assessments included 232 participants (intervention, *N* = 114;

control, $N = 118$) consisting of the following subgroups: intervention (physicians, $N = 30$; relatives, $N = 51$ and professional guardians, $N = 33$) and control (physicians, $N = 34$; relatives, $N = 49$ and professional guardians, $N = 35$).

Baseline characteristics were similar between trial arms (Table 1). Participants' mean age was 55.6 years (range 26–87) and 62.8% were female. The proportions of participants who had previously made a decision about antibiotic use varied by subgroup: physicians, 87.5%; relatives, 16.2% and professional guardians, 25.4%. The proportions of participants who had made a decision about artificial hydration use were: physicians, 89.1%; relatives, 15.2% and professional guardians, 13.4%.

Decisional conflict

Baseline decisional conflict scores were comparable between trial arms (Table 2). Relative to the control arm, participants in the intervention arm had significantly lower DCS-D scores related to decisions about antibiotics and artificial hydration at the one-month follow-up compared to at baseline. When participant subgroups were analyzed separately, DCS-D scores were significantly lower in the intervention arm, with the exception being professional guardians making decisions about artificial hydration (Table 2).

Table 1. Baseline characteristics of participants ($N = 232$) by Trial Arm

Characteristics	Intervention ($N = 114$) No. (%)	Control ($N = 118$) No. (%)
Participants		
Physicians	30 (26.3)	34 (28.8)
Relatives	51 (44.7)	49 (41.5)
Professional guardians	33 (28.9)	35 (29.7)
Age, year, mean \pm standard deviation ^a	56.1 \pm 14.1	55.0 \pm 13.5
Range	26–87	27–87
Female ^a	68 (59.6)	77 (65.3)
Religion ^a		
Protestant	52 (45.6)	42 (35.6)
Catholic	20 (17.5)	38 (32.2)
No religion	27 (23.7)	21 (17.8)
Other	14 (12.3)	15 (12.7)
Education of relative ^a		
\geq High school	50 (98.0)	45 (91.8)
Professional guardian's experience with dementia ^b	29 (87.9)	33 (94.3)
Prior decisions on ^{a,c}		
Antibiotics	41 (36.0)	48 (40.7)
Artificial hydration	39 (34.2)	42 (35.6)

^aTotal number of missing values by characteristics: age ($N = 1$), female ($N = 1$), religion ($N = 3$), education of relative ($N = 1$) and prior decisions on antibiotics ($N = 2$) and artificial hydration ($N = 2$).

^bProfessional guardians reported whether they had previously served as a legal guardian for a person with dementia.

^cParticipants reported whether they had previously made a decision about the use of antibiotics and/or artificial hydration for a person with dementia.

Knowledge

Baseline knowledge scores were comparable between trial arms (Table 3). Relative to the control arm, participants in the intervention arm scored significantly higher on the knowledge questions related to the use of antibiotics and artificial hydration at the 1-month follow-up compared to at baseline. Knowledge scores were significantly higher in the intervention arm for each participant subgroup for both treatment conditions (Table 3).

Preferences to forego interventions

Baseline decisions on antibiotic use were comparable between trial arms and distributed as follows (Table 3): $N = 80/229$ (34.9%); forego, $N = 101/229$ (44.1%) and undecided, $N = 48/229$ (21.0%). Baseline decisions on artificial hydration use were also comparable and had the following distribution: use, $N = 46/231$ (19.9%); forego, $N = 148/231$ (64.1%) and undecided, $N = 37/231$ (16.0%).

Relative to the control arm, participants who received the Fact Box in the intervention arm were significantly more likely to prefer to forego antibiotics at the one-month follow-up compared to at baseline. The intervention did not significantly impact preferences to forego artificial hydration, and treatment preferences did not differ when analyzed separately in each subgroup.

Acceptability of fact boxes

Among intervention participants, 86.8% ($N = 99/114$) and 75.4% ($N = 86/114$) found the Fact Boxes to be 'helpful' or 'rather helpful', respectively. Most participants rated the content as 'very good' or 'good' (antibiotics, $N = 79/112$ (70.5%); artificial hydration, $N = 76/112$ (67.9%)). Similarly, most participants positively rated the layout (antibiotics, $N = 91/113$ (80.5%); artificial hydration, $N = 88/113$ (77.9%)). While 64.3% ($N = 72/112$) of participants rated the amount of information in both Fact Boxes as 'exactly right', 34.8% ($N = 39/112$) and 33.9% ($N = 38/112$) found the information to be 'too little' in the antibiotic and artificial hydration Fact Boxes, respectively. All but one physician ($N = 29/30$, (96.7%)) were agreeable to using Fact Boxes in practice (agree, $N = 16/30$ (53.3%); somewhat agree, $N = 13/30$ (43.3%)).

Discussion

In this RCT, participants who received Fact Box decision support tools in the intervention arm showed significantly less decisional conflict about the use of antibiotics for pneumonia and artificial hydration in advanced dementia at the one-month follow-up compared to at baseline and relative to participants in the control arm. Fact Box recipients also showed greater knowledge about the use of these treatments and were more likely to prefer to forego antibiotics. However, the intervention did not impact preferences to withhold artificial hydration. Most users rated the Fact Boxes positively on helpfulness, content, layout and length,

Decision support tools for antibiotics and artificial hydration in advanced dementia

Table 2. The effects of Fact Box decision support tools on participants' decisional conflict^a about the use of antibiotics for pneumonia and artificial hydration in advanced dementia ($N = 232$)

Participants	Baseline Decisional Conflict ^b Mean \pm Standard Deviation			1-Month Decisional Conflict Mean \pm Standard Deviation		Intervention Effect ^c Unstandardized beta (95% Confidence Interval)
	Intervention	Control	<i>P</i> value	Intervention, Review Fact Boxes	Control	
All, No. ^d	114	118		114	118	
Decisional conflict about						
Antibiotic use	38.5 \pm 18.0	39.0 \pm 21.1	0.84	28.7 \pm 16.5	37.2 \pm 20.3	-8.35 (-12.43, -4.28)***
Artificial hydration use	36.4 \pm 17.9	36.9 \pm 20.4	0.86	30.1 \pm 17.8	36.0 \pm 19.0	-6.02 (-9.84, -2.20)**
Physicians, No. ^d	30	34		30	34	
Decisional conflict about						
Antibiotic use	32.8 \pm 12.4	29.3 \pm 14.1	0.30	26.0 \pm 13.7	28.3 \pm 12.5	-5.90 (-11.48, -0.32)*
Artificial hydration use	30.4 \pm 17.0	26.5 \pm 15.1	0.35	25.4 \pm 13.2	27.0 \pm 13.2	-6.41 (-12.11, -0.65)*
Relatives, No. ^d	51	49		51	49	
Decisional conflict about						
Antibiotic use	33.5 \pm 16.5	39.8 \pm 24.5	0.15	23.5 \pm 15.9	35.9 \pm 21.4	-8.02 (-14.81, -1.16)*
Artificial hydration use	33.5 \pm 15.3	37.1 \pm 20.9	0.36	23.5 \pm 14.7	33.5 \pm 17.6	-8.73 (-14.42, -3.02)**
Professional Guardians, No. ^d	33	35		33	35	
Decisional conflict about						
Antibiotic use	51.2 \pm 18.8	47.8 \pm 17.9	0.46	39.4 \pm 15.2	48.1 \pm 20.4	-10.96 (-19.34, -2.65)*
Artificial hydration use	45.9 \pm 18.8	47.3 \pm 19.4	0.78	44.6 \pm 17.8	46.4 \pm 21.1	-1.31 (-9.60, 7.02)

^aThe validated German version of the Decisional Conflict Scale (DCS-D), range 0–100, higher scores indicate greater conflict.

^bBaseline differences were analyzed using independent t-tests or chi-squared tests for continuous or categorical variables, respectively.

^cThe Fact Box effects were analyzed using linear mixed-effects models, which accounted for repeated measurements among individuals. **P* value < 0.05; ***P* value < 0.01 and ****P* value < 0.001.

^dMissing values are shown in Appendix 8 in Supplementary data, available in *Age and Ageing* online.

and 97% of physicians stated that they would use them as a communication tool.

This RCT builds upon limited prior research examining the effects of decision support tools in advanced dementia [12–18]. The findings corroborate the beneficial impact of these instruments on reducing decisional conflict [12, 13, 15]. Although decisional conflict was highest in non-physicians, the intervention still significantly reduced physicians' decisional conflict. Furthermore, the reduction on decisional conflict we observed with our brief tool was similar to that of a more intense 20-minute decision support tool [15]. Compared to video-based supports [14, 16–18], Fact Boxes are brief, handy, inexpensive and easier to incorporate into real-life care settings.

Fact Boxes are unique in that they can be used by a variety of decision-makers, such as physicians, relatives of dementia patients and professional guardians. This is evident by our findings that decisional conflict and knowledge improved in all of these different groups, compared to other tools designed for only one category of decision-makers [12–15]. All but one physician ($N = 29/30$) were agreeable to using Fact Boxes in practice, which is consistent with a prior study demonstrating the appeal of brief decision support tools to physicians [29]. Our findings that Fact Boxes aided professional guardians is particularly notable because it was relatively unknown what type of decision support they would benefit from when making end-of-life choices for patients [30]. The finding that one Fact Box impacted preferences to forego antibiotics is also noteworthy, as it suggests

comfort-focused care can be promoted by a less time intensive decision support tool than previously identified [14–18].

Several limitations merit discussion. First, our recruitment process resulted in lower participation rates than studies that recruited from medical institutions [12, 15]. Therefore, our findings cannot be generalized to eligible non-participants. Second, generalizability is also limited to the Swiss-German region of Switzerland and to hypothetical decisions. The effect of the intervention may vary in other regions and in real-world situations. Third, insufficient evidence regarding artificial hydration use in advanced dementia could explain why the Fact Box on this topic did not significantly impact decisions. Further research is certainly needed to determine the effects of artificial hydration in this population. In addition, it would be interesting to further investigate which particular part of the information provided in the Fact Boxes most influenced decisions and why. Lastly, the statistical power may have been insufficient to detect significant differences in subgroups (e.g. decisional conflict about artificial hydration use in professional guardians) and secondary outcomes (e.g. preferences to forego artificial hydration).

In this RCT, Fact Box decision support tools reduced participants' decisional conflict in hypothetical scenarios about the use of antibiotics for pneumonia and artificial hydration in advanced dementia. Both Fact Boxes increased participants' knowledge about each treatment and the Fact Box on antibiotics led to an increase in preferences to withhold this intervention. Through improving the quality of decision-making for a variety of decision-makers, potentially

Table 3. The effects of Fact Box decision support tools on participants' knowledge about the use of antibiotics for pneumonia and artificial hydration in advanced dementia and on preferences to Forego these interventions ($N = 232$)

Participants	Baseline ^a No. (%) or Mean \pm Standard Deviation			1-Month No. (%) or Mean \pm Standard Deviation		Intervention Effects ^b Unstandardized beta (95% Confidence Interval)
	Intervention	Control	<i>P</i> value	Intervention, Review Fact Boxes	Control	
All, No. ^c	114	118		114	118	
Knowledge about ^d						
Antibiotic use	3.0 \pm 1.8	2.9 \pm 1.7	0.65	5.3 \pm 1.7	3.0 \pm 1.8	2.24 (1.79, 2.68)***
Artificial hydration use	2.7 \pm 2.0	2.7 \pm 1.8	0.95	5.8 \pm 1.2	2.8 \pm 1.8	3.01 (2.53, 3.49)***
Preferences to forego ^e						
Antibiotic use	49 (43.4)	52 (44.8)	0.93	78 (69.0)	60 (50.8)	2.29 (1.08, 4.84) ^f
Artificial hydration use	73 (64.0)	75 (64.1)	>0.99	82 (72.6)	84 (71.2)	1.07 (0.49, 2.36) ^f
Physicians, No. ^c	30	34		30	34	
Knowledge about ^d						
Antibiotic use	4.2 \pm 1.5	4.6 \pm 1.4	0.33	6.4 \pm 0.9	4.9 \pm 1.5	1.90 (1.21, 2.59)***
Artificial hydration use	4.8 \pm 1.1	4.4 \pm 1.0	0.13	6.0 \pm 0.8	4.7 \pm 1.2	0.94 (0.33, 1.54)**
Preferences to forego ^e						
Antibiotic use	14 (46.7)	18 (52.9)	0.80	22 (73.3)	21 (61.8)	2.19 (0.51, 9.33) ^f
Artificial hydration use	26 (86.7)	25 (73.5)	0.32	27 (90.0)	27 (79.4)	1.00 (0.14, 7.01) ^f
Relatives, No. ^c	51	49		51	49	
Knowledge about ^d						
Antibiotic use	2.7 \pm 1.9	2.3 \pm 1.3	0.18	5.1 \pm 1.5	2.3 \pm 1.1	2.41 (1.73, 3.09)***
Artificial hydration use	2.0 \pm 1.8	2.0 \pm 1.6	>0.99	5.9 \pm 1.1	1.9 \pm 1.4	4.00 (3.30, 4.70)***
Preferences to forego ^e						
Antibiotic use	31 (60.8)	25 (52.1)	0.50	42 (84.0)	29 (59.2)	2.54 (0.74, 8.76) ^f
Artificial hydration use	34 (66.7)	30 (61.2)	0.72	39 (78.0)	34 (69.4)	1.23 (0.36, 4.18) ^f
Professional Guardians, No. ^c	33	35		33	35	
Knowledge about ^d						
Antibiotic use	2.4 \pm 1.3	2.2 \pm 1.5	0.67	4.6 \pm 1.9	2.1 \pm 1.5	2.34 (1.38, 3.30)***
Artificial hydration use	2.1 \pm 1.6	2.1 \pm 1.7	0.95	5.6 \pm 1.5	2.2 \pm 1.5	3.37 (2.43, 4.32)***
Preferences to forego ^e						
Antibiotic use	4 (12.5)	9 (26.5)	0.26	14 (42.4)	10 (28.6)	4.64 (0.90, 23.95) ^f
Artificial hydration use	13 (39.4)	20 (58.8)	0.18	16 (48.5)	23 (65.7)	1.08 (0.27, 4.29) ^f

^aBaseline differences were analyzed using independent t-tests or chi-squared tests for continuous or categorical variables, respectively.

^bThe Fact Box effects were analyzed using linear mixed-effects or logistic regression models for continuous or categorical variables, respectively. The mixed-effects models accounted for repeated measurements among individuals. **P* value < 0.05; ***P* value < 0.01 and ****P* value < 0.001.

^cMissing values are shown in Appendix 9 in Supplementary data, available in *Age and Ageing* online.

^dKnowledge was ascertained using 7-item true-false questions specific to the use of each treatment (scored, 1 = true, 0 = false/don't know; range 0–7, higher scores indicate greater knowledge). The questions and proportions of correct responses per item are shown in Appendices 5 and 6 in Supplementary data, available in *Age and Ageing* online.

^ePreferences to use antibiotics and artificial hydration were measured using single questions with response options: 'use', 'forego' or 'undecided'.

^fUnstandardized beta for categorical variables were transformed into odds ratios.

promoting less aggressive care and providing physicians with a useful communication tool, Fact Boxes may be a promising decision support tool for real-world settings. The next step is therefore to determine their effects in health care facilities.

Key points

- Fact Box decision support tools about the use of antibiotics for pneumonia and artificial hydration in advanced dementia were developed.
- Fact Boxes improve decision-making outcomes of physicians, relatives of dementia patients and professional guardians.
- Fact Boxes can aid a variety of decision-makers and are a promising, brief and inexpensive tool for real-life settings.

Supplementary data

Supplementary data mentioned in the text are available to subscribers in *Age and Ageing* online.

Acknowledgements

The investigators wish to thank Dr van der Maaden, Dr van der Steen and the researchers of the Harding Center for Risk Literacy at the Max Planck Institute for Human Development for their collaboration in developing the Fact Boxes. The investigators also thank the data management team (Daniel Gfeller and Kathrin Heiniger), the organizations' staff that helped with recruitment, and the participants who have given their time to this study.

Conflict of interest

None.

Funding

This work was supported by the following grants: the ‘Research in Palliative Care’ funding program [PC 22/14], which was offered jointly by the Swiss Academy of Medical Sciences, the Stanley Thomas Johnson Foundation and the Gottfried and Julia Bangerter-Rhyner Stiftung; the Swiss National Science Foundation [P1ZHP3_171747 to AJL]; and the United States National Institute of Health—National Institute on Aging [NIH-NIA R01 AG032982, NIH-NIA R01 AG043440, NIH-NIA K24AG033640 to SLM].

References

- World Health Organization. The epidemiology and impact of dementia: current state and future trends. http://www.who.int/mental_health/neurology/dementia/dementia_thematicbrief_epidemiology.pdf. Accessed April 26, 2018.
- Mitchell SL, Teno JM, Kiely DK *et al*. The clinical course of advanced dementia. *N Engl J Med* 2009; 361: 1529–38.
- van der Steen JT, Mehr DR, Kruse RL *et al*. Predictors of mortality for lower respiratory infections in nursing home residents with dementia were validated transnationally. *J Clin Epidemiol* 2006; 59: 970–9.
- Mitchell SL, Shaffer ML, Loeb MB *et al*. Infection management and multidrug-resistant organisms in nursing home residents with advanced dementia. *JAMA Intern Med* 2014; 174: 1660–7.
- Givens JL, Jones RN, Shaffer ML, Kiely DK, Mitchell SL. Survival and comfort after treatment of pneumonia in advanced dementia. *Arch Intern Med* 2010; 170: 1102–7.
- Pasman HRW, Onwuteaka-Philipsen BD, Kriegsman DMW, Ooms ME, Ribbe MW, van der Wal G. Discomfort in nursing home patients with severe dementia in whom artificial nutrition and hydration is forgone. *Arch Intern Med* 2005; 165: 1729–35.
- Pasman HRW, Onwuteaka-Philipsen BD, Kriegsman DMW, Ooms ME, van der Wal G, Ribbe MW. Predictors of survival in nursing home patients with severe dementia in whom artificial nutrition and hydration forgone. *Int Psychogeriatr* 2006; 18: 227–40.
- van der Steen JT, Lane P, Kowall NW, Knol DL, Volicer L. Antibiotics and mortality in patients with lower respiratory infection and advanced dementia. *J Am Med Dir Assoc* 2012; 13: 156–61.
- Engel SE, Kiely DK, Mitchell SL. Satisfaction with end-of-life care for nursing home residents with advanced dementia. *J Am Geriatr Soc* 2006; 54: 1567–72.
- Givens JL, Kiely DK, Carey K, Mitchell SL. Healthcare proxies of nursing home residents with advanced dementia: decisions they confront and their satisfaction with decision-making. *J Am Geriatr Soc* 2009; 57: 1149–55.
- Mitchell SL, Palmer JA, Volandes AE, Hanson LC, Habtemariam D, Shaffer ML. Level of care preferences among nursing home residents with advanced dementia. *J Pain Symptom Manage* 2017; 54: 340–5.
- Mitchell SL, Tetroe J, O’Connor AM. A decision aid for long-term tube feeding in cognitively impaired older persons. *J Am Geriatr Soc* 2001; 49: 313–6.
- Snyder EA, Caprio AJ, Wessell K, Lin FC, Hanson LC. Impact of a decision aid on surrogate decision-makers’ perceptions of feeding options for patients with dementia. *J Am Med Dir Assoc* 2013; 14: 114–8.
- Einterz SF, Gilliam R, Lin FC, McBride JM, Hanson LC. Development and testing of a decision aid on goals of care for advanced dementia. *J Am Med Dir Assoc* 2014; 15: 251–5.
- Hanson LC, Carey TS, Caprio AJ *et al*. Improving decision-making for feeding options in advanced dementia: a randomized, controlled trial. *J Am Geriatr Soc* 2011; 59: 2009–16.
- Hanson LC, Zimmerman S, Song M-K *et al*. Effect of the goals of care intervention for advanced dementia: a randomized clinical trial. *JAMA Intern Med* 2017; 177: 24–31.
- Volandes AE, Paasche-Orlow MK, Barry MJ *et al*. Video decision support tool for advance care planning in dementia: randomised controlled trial. *BMJ* 2009; 338: b1964.
- Mitchell SL, Shaffer ML, Cohen S, Hanson LC, Habtemariam D, Volandes AE. An advance care planning video decision support tool for nursing home residents with advanced dementia: a cluster randomized clinical trial. *JAMA Intern Med* 2018; 178:961–9. doi:10.1001/jamainternmed.2018.1506.
- Schwartz LM, Woloshin S, Welch HG. Using a drug facts box to communicate drug benefits and harms: two randomized trials. *Ann Intern Med* 2009; 150: 516–27.
- McDowell M, Rebitschek FG, Gigerenzer G, Wegwarth O. A simple tool for communicating the benefits and harms of health interventions: a guide for creating a fact box. *MDM Policy Practice* 2016; 1: 1–10.
- Center for Gerontology, University of Zurich. Fact box decision support tools for the use of antibiotics for pneumonia and artificial hydration in advanced dementia. <http://www.zfg.uzh.ch/en/projekt/demfacts.html>. Accessed April 26, 2018.
- Elwyn G, O’Connor A, Stacey D *et al*. Developing a quality criteria framework for patient decision aids: online international Delphi consensus process. *BMJ* 2006; 333: 417–9.
- van der Maaden T, van der Steen JT, de Vet HCW, Hertogh CPM, Koopmans RTCM. Prospective observations of discomfort, pain, and dyspnea in nursing home residents with dementia and pneumonia. *J Am Med Dir Assoc* 2016; 17: 128–35.
- Mitchell SL. Advanced dementia. *N Engl J Med* 2015; 372: 2533–40.
- Gabriel MS, Tschanz JA. Artificial nutrition and hydration. In: Ferrell BR, Coyle N, Paice J, eds. *Oxford Textbook of Palliative Nursing*, 4 ed. New York: Oxford University Press, 2015.
- O’Connor AM. Validation of a decisional conflict scale. *Med Decis Making* 1995; 15: 25–30.
- Buchholz A, Hölzel L, Kriston L, Simon D, Härter M. Die decisional conflict scale in deutscher Sprache (DCS-D): dimensionale

- Struktur in einer Stichprobe von Hausarztpatienten. *Klin Diagnostik u Evaluation* 2011; 4: 15–30.
28. R Core Team. R: A language and environment for statistical computing. Vienna, Austria: R Foundation for Statistical Computing, 2016. URL: <https://www.R-project.org/>.
29. Giguere AMC, Labrecque M, Légaré F *et al.* Feasibility of a randomized controlled trial to evaluate the impact of decision

boxes on shared decision-making processes. *BMC Med Inform Decis Mak* 2015; 15: 1–10.

30. Cohen AB, Wright MS, Cooney L, Fried T. Guardianship and end-of-life decision making. *JAMA Intern Med* 2015; 175: 1687–91.

Received 15 March 2018; editorial decision 17 July 2018

Age and Ageing 2019; 48: 74–80
doi: 10.1093/ageing/afy163
Published electronically 2 October 2018

© The Author(s) 2018. Published by Oxford University Press on behalf of the British Geriatrics Society. All rights reserved. For permissions, please email: journals.permissions@oup.com

Frequency, intensity and localization of pain as risk factors for frailty in older adults

ISABEL RODRÍGUEZ-SÁNCHEZ^{1,2†}, ESTHER GARCÍA-ESQUINAS^{1,3†}, ARTHUR E. MESAS⁴,
JOSÉ MARÍA MARTÍN-MORENO⁵, LEOCADIO RODRÍGUEZ-MAÑAS⁶, FERNANDO RODRÍGUEZ-ARTALEJO^{1,3,7}

¹Department of Preventive Medicine and Public Health, School of Medicine, Universidad Autónoma de Madrid/IdiPaz, Madrid, Spain

²Department of Geriatric Medicine, Hospital Universitario La Paz/IdiPaz, Madrid, Spain

³CIBERESP (CIBER of Epidemiology and Public Health), Madrid, Spain

⁴Department of Public Health, Universidade Estadual de Londrina, Londrina, Brazil

⁵Preventive Medicine and Public Health and University Clinical Hospital INCLIVA, University of Valencia, Valencia, Spain

⁶Department of Geriatric Medicine, Hospital Universitario de Getafe and CIBERFES (CIBER of Frailty and Healthy Ageing), Getafe, Spain

⁷IMDEA-Food Institute, CEI UAM+CSIC, Madrid, Spain

Address correspondence to: Esther García-Esquinas, MD, Department of Preventive Medicine and Public Health, School of Medicine, Universidad Autónoma de Madrid. Calle del Arzobispo Morcillo 4, 28029 Madrid, Spain. Tel: (+34) 91-497-27-61, Fax: (+34) 91-497-53-53, Email: esthergge@gmail.com

[†]Both authors have contributed equally to this manuscript.

Abstract

Background: the association between pain characteristics and frailty risk is uncertain.

Objective: to investigate the separate impact of the frequency, intensity and location of pain on frailty risk and its possible mechanisms.

Methods: prospective cohort of 1505 individuals ≥ 63 years followed between 2012 and 2015 in Spain. In 2012, pain was classified into: lowest pain (Score 0), middle pain (Score 1–4) and highest pain (Score 5–6). Incident frailty was assessed in 2015 as having ≥ 3 Fried criteria or a Frailty Index (FI) ≥ 0.30 .

Results: in multivariate analyses, the risk of frailty (measured with the Fried criteria or the FI) increased progressively with the frequency of pain, its intensity and the number of pain locations. Compared with those having the lowest pain score, the odds ratio (95% confidence interval) of Fried-based frailty was 1.24 (0.56–2.75) in the middle score and 2.39 (1.34–4.27; P -trend < 0.01) in the highest score. Corresponding values for frailty as FI ≥ 0.30 were 1.39 (0.80–2.42) and 2.77 (1.81–4.24; P -trend < 0.01). Odds ratios did not change after adjustment for alcohol intake, Mediterranean diet adherence or sedentary time, but were reduced with adjustment for pain-associated chronic diseases (cardiovascular disease, diabetes, chronic lung disease, osteomuscular disease and depression). A higher pain score was linked to higher risk of exhaustion and low physical activity (two out of five Fried criteria) and to a worse score in all FI domains.