

ORIGINAL RESEARCH

Level of Effort and 3 Hour Rule Compliance

Cynthia L. Beaulieu, PhD, ABPP,^a Juan Peng, MAS,^b Erinn M. Hade, PhD,^b
John D. Corrigan, PhD, ABPP,^b Ronald T. Seel, PhD,^c Marcel P. Dijkers, PhD, FACRM,^{d,e}
Flora M. Hammond, MD, FACRM,^f Susan D. Horn, PhD,^g Misti L. Timpson, PT, DPT, NCS,^h
Melanie Swan, MBA, OTR/L,ⁱ Jennifer Bogner, PhD, ABPP^b

From the ^aBrooks Rehabilitation Hospital, Jacksonville, Florida; ^bThe Ohio State University College of Medicine, Columbus, Ohio; ^cCenter for Rehabilitation Science and Engineering, Virginia Commonwealth University School of Medicine, Richmond, Virginia; ^dIcahn School of Medicine at Mount Sinai, New York, New York; ^eWayne State University, Detroit, Michigan; ^fIndiana University School of Medicine, Indianapolis, Indiana; ^gInstitute for Clinical Outcomes Research and University of Utah School of Medicine, Salt Lake City, Utah; ^hRocky Mountain University of Health Professions, Provo, Utah; and ⁱOhio State University Wexner Medical Center, Columbus, Ohio, the United States.

Abstract

Objective: To determine if patients' level of effort (LOE) in therapy sessions during traumatic brain injury (TBI) rehabilitation modifies the effect of compliance with the 3-Hour Rule of the Centers for Medicare & Medicaid Services.

Design: Propensity score methodology applied to the TBI Practice-Based Evidence database, consisting of multisite, prospective, longitudinal observational data.

Setting: Acute inpatient rehabilitation facilities (IRF).

Participants: Patients (N=1820) who received their first IRF admission for TBI in the United States and were enrolled for 3- and 9-month follow-up.

Main Outcome Measures: Participation Assessment with Recombined Tools-Objective-17, FIM Motor and Cognitive scores, Satisfaction with Life Scale, and Patient Health Questionnaire-9.

Results: When the full cohort was examined, no strong main effect of compliance with the 3-Hour Rule was identified and LOE did not modify the effect of compliance with the 3-Hour Rule. In contrast, LOE had a strong positive main effect on all outcomes, except depression. When the sample was stratified by level of disability, LOE modified the effect of compliance, particularly on the outcomes of participants with less severe disability. For these patients, providing 3 hours of therapy for 50% or more of therapy days in the context of low effort resulted in poorer performance on select outcome measures at discharge and up to 9 months postdischarge compared to patients with <50% of 3-hour therapy days.

Conclusions: LOE is an active ingredient in inpatient TBI rehabilitation, while compliance with the 3-Hour Rule was not found to have a substantive effect on the outcomes. The results support matching time in therapy during acute TBI rehabilitation to patients' LOE in order to optimize long-term benefits on outcomes.

Archives of Physical Medicine and Rehabilitation 2019; ■: ■ ■ ■ ■ - ■ ■ ■ ■

© 2019 Published by Elsevier Inc. on behalf of the American Congress of Rehabilitation Medicine

Presented to the Federal Interagency Conference on Traumatic Brain Injury, June 12, 2018, City, State.

Supported by the Patient-Centered Outcomes Research Institute (grant no. CER-1403-13476), the National Institutes of Health, National Center for Medical Rehabilitation Research (grant no. 1R01HD050439-01), the National Institute on Disability, Independent Living, and Rehabilitation Research (grant no. H133A080023), and the Ontario Neurotrauma Foundation (grant no. 2007-ABI-ISIS-525). The statements presented in this work are solely the responsibility of the authors and do not necessarily represent the views of the Patient-Centered Outcomes Research Institute, its Board of Governors, or Methodology Committee.

Disclosures: none.

In 1982, the Centers for Medicare & Medicaid Services (CMS) imposed a regulatory requirement on inpatient rehabilitation facilities (IRF) to provide 3 hours of therapy per day.¹ The *3-Hour Rule* mandates that to qualify for Medicare-paid IRF-level reimbursement of rehabilitation costs, IRFs must provide a minimum of 3 hours per day of either occupational therapy (OT) or physical therapy (PT) and 1 additional therapy, usually speech therapy (ST)

for 5 of 7 days or 15 hours per week.¹ The rule is mandatory for CMS-affiliated payers, but it is not uncommon for other payers to establish similar expectations for quantity of time in therapies. Understanding whether the level of therapeutic intensity, as measured by time, is associated with the best acute inpatient rehabilitation outcomes is critical to both consumers of rehabilitation and to providers.^{2,3}

The 3-Hour Rule was imposed before securing substantive evidence indicating time in therapy alone affects outcomes. An early study conducted in 1986 suggested the rule may increase costs without appreciable improvements in outcomes.² A Cochrane systematic review of interdisciplinary rehabilitation for stroke and traumatic brain injury (TBI) concluded there is strong evidence that more intensive treatment leads to earlier functional gains, and moderate evidence for it shortening length of stay (LOS).³ However, the effect on longer-term outcomes (eg, 6-12mo postinjury) was not significant or was insufficiently studied. Also, the review was based on 4 randomized controlled trials conducted in the 1990s, in countries whose systems of care differ substantially from current rehabilitation in the United States, using varying definitions of treatment intensity across the studies. A more recent meta-analysis calculated a medium effect size for intensity of rehabilitation.⁴ However, the analysis included 2 of the studies from the previous systematic review and the remaining 3 were not conducted in an IRF setting or did not involve multidisciplinary rehabilitation. Two studies conducted with patients receiving stroke rehabilitation found ≥ 3 hours of therapy per day was associated with greater functional gain at discharge⁵ and shorter LOS.⁶ Studies varied in either collection or analysis of potential confounding variables such as age, severity, and time postevent. Despite substantial changes in rehabilitation care and payment systems, no controlled studies in the past 18 years include patients with TBI treated in IRFs in the United States.

Recent research focuses on defining therapy intensity as a function of the complexity of therapeutic activity rather than as treatment time per se, and on identifying factors that may affect a patient's ability to participate in therapy sessions. Horn et al⁷ found greater effort extended by patients with TBI within therapy sessions and more time spent in complex therapy activities were associated with better outcomes at IRF discharge and similar, less pervasive associations at 9 months postdischarge. Recent research suggests the amount of effort patients are able to expend, and the content of therapy, may be the important active ingredients

of rehabilitation.^{8,9} For individuals with TBI, the severity of the presenting disability is an important factor influencing the ability to participate effortfully in treatment, as well as responsiveness to different therapeutic approaches.¹⁰

The present study is one of a series utilizing propensity score methodology to control measured confounders while evaluating rehabilitation approaches and methods of delivery. We hypothesized that patients' level of effort (LOE) during therapy sessions modifies the effect of compliance with the 3-Hour Rule. Given that the severity of the presenting disability has been found to influence effort in treatment, we planned a priori to evaluate effect modification in groups stratified by severity in addition to the full cohort. The study provides a preliminary examination of possible causal relationships between compliance with the 3-Hour Rule, how compliance may be modified by LOE, and outcomes up to 9 months postdischarge from inpatient rehabilitation.

Methods

This study analyzes data from the multisite longitudinal TBI Practice-Based Evidence (TBI-PBE) study that enrolled consecutive IRF admissions from 2008 to 2011 at 9 United States sites and 1 in Canada.¹¹ The TBI-PBE Database incorporates data abstracted from medical records, point-of-care (POC) documentation of IRF treatments, and follow-up interviews. During each therapy session, trained therapists using standardized POC forms recorded time in each therapeutic activity and LOE expended by the patient.

Participants

The portion of the TBI-PBE Database used in the current analysis included 1820 participants who were: (1) aged 14 years or older; (2) received their first IRF admission for TBI rehabilitation at a United States facility; (3) consented to follow-up; (4) received therapy after the first 3 days of the admission; and (5) had valid LOE ratings (ie, were not missing LOE or were not in a minimally conscious state throughout the admission). This information is listed in [supplemental appendix S1](#) (available online only at <http://www.archives-pmr.org/>). An additional 8 participants were excluded because they did not receive weights in the propensity score model due to missing values on key variables.

Setting

The IRFs that participated in the TBI-PBE study are described by Seel et al.¹²

The 9 facilities in the United States were CMS-compliant with the 3-Hour Rule, typically delivering 3 hours across the 5 weekdays or delivering 15 hours across a 7-day week by exception. The mean session length was 38.6 minutes (mean time \pm SD [min], 38.6 ± 8.7) for PT, 37.7 ± 7.7 for OT, and 32.5 ± 6.1 for ST. Patients received the majority of their therapy during the week, with a median of 0.3 hours of PT and OT and 0.2 hours of ST provided on the weekend.

Severity stratification

To evaluate heterogeneity of treatment effects, the sample was stratified into 2 groups based on severity of disability at admission. The severe group consisted of patients who required maximal

List of abbreviations:

ASD	absolute standardized difference
CI	confidence interval
CMS	Centers for Medicare & Medicaid Services
IPW	inverse probability weighting
IRF	inpatient rehabilitation facility
LOE	level of effort
LOS	length of stay
OT	occupational therapy
PART-O	Participation Assessment with Recombined Tools-Objective
POC	point of care
PT	physical therapy
ST	speech therapy
SWLS	Satisfaction with Life Scale
TBI	traumatic brain injury
TBI-PBE	Traumatic Brain Injury Practice-Based Evidence

assistance with all self-care, mobility, and cognitive needs (FIM Cognitive scores at admission ≤ 15 and FIM Motor scores < 28.75 , $n = 805$). The less severe group comprised the remaining patients ($n = 1015$).

Level of effort

Effort during each session was rated by the rehabilitation therapists with the Rehabilitation Intensity of Therapy Scale,⁸ a single-item, behaviorally anchored, 7-point scale. Higher scores indicate more patient engagement and effort, with effort being operationally defined as being attentive and engaged in goal-directed activity, including initiating activity, incorporating therapist feedback, and persevering when therapies become challenging.¹⁰ A number of steps were taken to minimize rater variability, bias and missing data. Therapists were trained in using the Rehabilitation Intensity of Therapy Scale LOE ratings and tested twice during the study for accuracy. High accuracy rates (% correct responses) were observed at the initial testing for ST (98%), PT (97%), and OT (89%); they remained high at the 9-month follow-up test for ST (91%), PT (91%), and OT (81%).¹⁰ The LOE ratings across ST, PT, and OT individual therapy sessions closely conformed to a normative distribution with minimal skewness (-0.02 to -0.11) and kurtosis (-0.08 to -0.12). Test-retest stability for the single-item LOE ratings were excellent for all 3 disciplines during both morning and afternoon sessions, with intraclass correlation coefficients ranging from 0.76 to 0.80.¹⁰ For the current study, LOE was averaged across disciplines and days of the rehabilitation stay.

Compliance with 3-Hour Rule

Hours of therapy per day were calculated from the minutes recorded on the POC forms, and used to determine the percentage of rehabilitation days in compliance with the 3-Hour Rule. (Calculation details are provided in [supplemental appendix S2](http://www.archives-pmr.org/), available online only at <http://www.archives-pmr.org/>.) The distribution of percentage of days in compliance with the 3-Hour Rule distinguished 3 groups of participants: (1) 3 hours or more of therapy on 50% or more of days (50%+ compliant); (2) 3 hours or more on 20% to 50% of days (20%-50% compliant); and (3) 3 hours or more on 0% to 20% of days (0%-20% compliant). Percentage of therapy time in group treatment and total number of therapy hours over the entire rehabilitation stay were calculated and used in sensitivity analyses.

Outcomes

Outcome data were collected at discharge (FIM¹³ only), and 3 and 9 months postdischarge. The primary outcome was community participation, as measured by the Participation Assessment with Recombined Tools-Objective-17 (PART-O)-17.^{14,15} This study used the 3 domain scores (Out and About, Social Relations, Productivity), the total score derived from the 3 domain scores, and a Rasch-adjusted total score that measures participation on a ratio scale.¹⁶ Secondary outcomes included the FIM Rasch-adjusted Motor and Cognitive scores,¹⁷ the Patient Health Questionnaire-9¹⁸ dichotomized into likely major depression vs no major depression,¹⁹ and the Satisfaction with Life Scale (SWLS).²⁰ All of the measures have established psychometrics.²¹⁻²³

Potential confounders

To ensure characteristics considered potential confounders were not affected by the rehabilitation treatment, only variables measured at rehabilitation admission (first 3 days) or earlier were included in the propensity score adjustment model. The full list of potential confounders can be found in [supplemental table S3](http://www.archives-pmr.org/) (available online only at <http://www.archives-pmr.org/>).

Analysis

Data were analyzed using SAS v9.3^a and STATA version 14.0^b software. Inverse probability weighting (IPW) with generalized propensity scores estimated by multinomial logistic regression was used to control for measured confounders across the 3 compliance groups. An iterative process was used to develop models that achieved the optimal balance of potential confounders, including trials of interaction terms. Balance across the 3 compliance groups was assessed using the absolute standardized difference (ASD) between all possible pairs of groups²⁴ prior to and after weighting by the stabilized IPW. If, after IPW, the ASD for a potential confounder exceeded a conservative 0.10, the potential confounder was included as a covariate in the outcome analysis model.²⁴ The generalized propensity score model was estimated for the full cohort, and separately for the severe and less severe subgroups.

The hypothesis that LOE would modify the effect of compliance with the 3-Hour Rule was evaluated through marginal regression models weighted by the standardized IPW, with robust sandwich SE estimates. The potential modification by LOE of compliance's effect on outcomes was tested first by the interaction term between LOE and compliance (including effects of the lower-order terms), without including any covariates that were not balanced by IPW. In the second step, models were adjusted for any unbalanced covariates. Primary inference is based on and reported for the second step, because the first step was assumed to be biased by confounders. If effect modification was not significant at the $P < .05$ level, the interaction term was dropped and the main effects of compliance and of LOE were estimated.

Sensitivity analysis evaluated the proportion of time in group therapy and total therapy hours delivered over the LOS due to concerns that these factors might influence the effects of compliance. Multiple imputation (40 iterations) for all missing outcome measures was used to examine if findings were substantially more efficient (ie, reduced variance) in the full sample. Heterogeneity of treatment effects in the severe and less severe subgroups was evaluated by conducting analyses separately for these groups. When effects were observed in a subgroup, we compared confidence intervals (CIs) of effect sizes to determine if the size of the effects differed based on severity of disability. See [supplemental appendix S2](http://www.archives-pmr.org/) (available online only at <http://www.archives-pmr.org/>) for additional details regarding statistical methods.

Results

Full cohort

The extent to which confounders were balanced across compliance groups was evaluated by examining the ASDs for pairwise comparisons (listed in [table 1](http://www.archives-pmr.org/) and [supplemental table S3](http://www.archives-pmr.org/)). Prior to weighting, mean ASD was 0.13, with a maximum of 0.84. Forty-seven percent of the confounders or levels of a confounder (for

Table 1 Demographic and clinical characteristics at admission, by compliance with the 3-Hour Rule exposure groups, prior to, and with IPW

	Prior to IPW			With IPW			
	Compliance Group			Compliance Group			
	0%-20%	20%-50%	50%+	0%-20%	20%-50%	50%+	ASD*
Demographics							
Age at admission (y), mean ± SD	45.79±20.1	44.82±22.0	43.09±21.74	45±21.26	44.1±21.58	44.86±21.17	0.03
Male sex, n (%)	396 (74.72)	486 (71.89)	427 (69.32)	394.64 (74.96)	493.65 (72.09)	432.08 (72.47)	0.04
Race/ethnicity, n (%)							
White non-Hispanic	380 (71.7)	508 (75.15)	490 (79.55)	384.23 (72.99)	509.34 (74.38)	454.7 (76.26)	0.05
White Hispanic	38 (7.17)	47 (6.95)	29 (4.71)	31.19 (5.93)	40.69 (5.94)	28.94 (4.85)	0.03
Black	94 (17.74)	102 (15.09)	80 (12.99)	94.26 (17.91)	114.13 (16.67)	82.68 (13.87)	0.07
Other or unknown	18 (3.4)	19 (2.81)	17 (2.76)	16.74 (3.18)	20.59 (3.01)	29.92 (5.02)	0.07
At least high school education, n (%)	389 (73.4)	487 (72.04)	441 (71.59)	362.91 (68.94)	503.21 (73.49)	440.73 (73.92)	0.07
Insurance, n (%)							
Private/MCO/HMO	196 (36.98)	303 (44.82)	263 (42.69)	186.03 (35.34)	286.15 (41.79)	260.9 (43.76)	0.12
Medicare	115 (21.7)	152 (22.49)	122 (19.81)	122.12 (23.2)	146.46 (21.39)	124.48 (20.88)	0.04
Medicaid	118 (22.26)	87 (12.87)	110 (17.86)	101.8 (19.34)	122.59 (17.9)	87.91 (14.74)	0.08
Self-pay/other payer	76 (14.34)	91 (13.46)	76 (12.34)	79.11 (15.03)	91.4 (13.35)	73.54 (12.33)	0.05
Workers' compensation	25 (4.72)	43 (6.36)	45 (7.31)	37.36 (7.1)	38.14 (5.57)	49.39 (8.28)	0.07
Premorbid conditions							
Alcohol misuse, n (%)	259 (48.87)	215 (31.8)	177 (28.73)	199.9 (37.97)	244.93 (35.77)	176.16 (29.55)	0.12
Other drug use, n (%)	159 (30)	128 (18.93)	109 (17.69)	113.46 (21.55)	152.28 (22.24)	119.86 (20.1)	0.04
Injury and status at admission to rehabilitation							
Cause of injury, n (%)							
Fall	169 (31.89)	208 (30.77)	189 (30.68)	178.3 (33.87)	217.91 (31.82)	177.49 (29.77)	0.06
Sports	35 (6.6)	36 (5.33)	29 (4.71)	21.49 (4.08)	35.13 (5.13)	43.29 (7.26)	0.09
Motor vehicle	279 (52.64)	380 (56.21)	374 (60.71)	278.66 (52.93)	386.31 (56.42)	339.99 (57.02)	0.05
Violence	47 (8.87)	52 (7.69)	24 (3.9)	47.98 (9.11)	45.4 (6.63)	35.46 (5.95)	0.08
Site, n (%)							
Site group 1 [†]	28 (5.28)	223 (32.99)	190 (30.84)	140.19 (26.63)	168.36 (24.59)	152.26 (25.54)	0.03
Site group 2 [‡]	289 (54.53)	160 (23.67)	31 (5.03)	140.06 (26.61)	180.22 (26.32)	152.66 (25.61)	0.02
Site group 3 [§]	129 (24.34)	79 (11.69)	174 (28.25)	90.49 (17.19)	146.26 (21.36)	112.9 (18.94)	0.07
Site group 4	84 (15.85)	214 (31.66)	221 (35.88)	155.69 (29.57)	189.9 (27.73)	178.4 (29.92)	0.03
Time to rehabilitation (d), mean ± SD	24.35±33.52	26.2±30.03	28.81±32.4	31.15±41.93	27.15±29.02	26.17±28.52	0.09
FIM Motor at admission (Rasch), mean ± SD	36.16±16.62	31.64±16.76	25.63±17.28	32.23±16.11	31.22±17.63	30.69±16.22	0.06
FIM Cognitive at admission (Rasch), mean ± SD	39.85±19.22	37.89±18.06	30.68±19.32	36.55±19.13	35.6±19.55	36.42±18.87	0.03
Posttraumatic amnesia cleared prior to rehab admission, n (%)	243 (45.85)	246 (36.39)	163 (26.46)	180.29 (34.25)	245.97 (35.92)	189.52 (31.79)	0.06
CSI brain injury, mean ± SD	39.11±21.12	45.18±22.18	53.92±23.08	45.35±22.28	46.38±22.82	46.80±22.36	0.04
CSI nonbrain injury, mean ± SD	16.34±14.76	19.16±15.43	17.13±14.25	21.34±24.99	17.43±14.55	18.72±15.62	0.13

(continued on next page)

Table 1 (continued)

	Prior to IPW			With IPW		
	Compliance Group			Compliance Group		
	0%-20%	20%-50%	50%+	0%-20%	20%-50%	50%+
Glasgow Coma Score, n (%)						
Intubated/missing	285 (53.77)	300 (44.38)	277 (44.97)	263.09 (49.98)	313.92 (45.84)	273.75 (45.91)
Mild	99 (18.68)	96 (14.2)	69 (11.2)	71.74 (13.63)	105.89 (15.46)	95.69 (16.05)
Moderate-severe	146 (27.55)	280 (41.42)	270 (43.83)	191.6 (36.4)	264.94 (38.69)	226.79 (38.04)

Abbreviations: CSI, Comprehensive Severity Index; HMO, health maintenance organization; MCO, managed care organization; Rehab, rehabilitation.

* ASD of the 3, 2 group comparisons after IPW.

† Site group 1 consists of sites with less than 10% of participants receiving Medicare.

‡ Site group 2 consists of sites with 10-20% of participants receiving Medicare.

§ Site group 3 consists of sites with 20-30% of participants receiving Medicare.

|| Site group 4 consists of sites with >30% receiving Medicare.

categorical variables) had ASDs greater than 0.10. The estimated stabilized IPW had an average value of 0.99 (minimum: 0.30, maximum: 17.1). After weighting, the mean ASD was reduced to 0.06 (maximum=0.13) with 4% (n=3) of the variables had ASDs exceeding the 0.10 threshold. The 3 unbalanced confounders (Comprehensive Severity Index-Nonbrain Injury, premorbid alcohol misuse, private insurance) were included in the outcome analyses.

The hypothesis regarding the effect modification of LOE on compliance was tested first. Adjusting for the 3 unbalanced covariates, there was no significant effect modification between LOE and compliance with the 3-Hour Rule for any outcome. Given that the a priori hypothesis was not supported, the interaction term was dropped and the main effects were estimated. Compliance was associated with a significantly lower PART-O Social Relations score at 3 months for those with 20% to 50% compliance vs those with 50%+ compliance (adjusted average difference: 0%-20% compliance vs 50%+, -0.08; 95% CI, -0.29 to 0.12; 20%-50% compliance vs 50%+ compliance, -0.18; 95% CI, -0.31 to -0.04). However, after controlling for LOE, compliance was not strongly associated with any outcome (noted in table 2). LOE had a strong positive association (main effect) with all outcomes, except Patient Health Questionnaire-9 (see table 2). These findings did not change substantially when total number of therapy hours and percentage of treatment in group therapy were added to the model, with the exception of a weaker association with SWLS at 3 months. Following multiple imputation, SWLS at 3 months was again strongly associated with LOE.

Stratification by disability severity

For the severe subgroup, prior to weighting the mean ASD was 0.14 with a maximum of 0.75; 56% of variables had ASDs greater than 0.10. After weighting, the mean ASD was 0.10 (maximum=0.26) with 46% of variables (36/79) had ASD exceeding 0.10. After adjustment for unbalanced covariates, significant modification of the effect of compliance by LOE was noted for: FIM Cognitive at 3 months and PART-O Rasch total at 9 months (displayed in table 3 and fig 1 and 2). Post hoc analysis of the difference in outcomes between the compliance groups for each rating of LOE were significant for FIM Cognitive, but not for PART-O Rasch total. Findings did not change substantially when total therapy hours and percentage of group therapy were added to the models. For those outcomes for which a significant effect modification was not found, the main effect of compliance, adjusted for LOE, was examined. No significant main effects of compliance were identified.

For the less severe subgroup, before weighting the mean ASD was 0.12 with a maximum of 0.86; 42% of the variables had ASDs>0.10. After weighting, the mean ASD was 0.08 (maximum=0.19) with 29% of the variables with ASDs greater than 0.10. These 23 variables were included in the adjusted outcome analysis. LOE was found to significantly modify the effect of compliance on: PART-O total, total Rasch, and Social Relations at 9 months, Out and About at 3 and 9 months, Productivity at 3 months, SWLS at 3 and 9 months, and FIM Cognitive at discharge, after adjustment for unbalanced covariates (see table 3, fig 3-5 and supplemental fig S1-S5, available online only at <http://www.archives-pmr.org/>). Adding percent of group therapy and total therapy minutes to the models, the compliance effect modification by LOE was no longer significant at the $P<.05$ level for PART-O total Rasch at 9 months, Out and About at 3 months, and

Table 2 Full cohort, adjusted main effects of LOE and compliance with the 3-Hour Rule

Outcome	Time Point	LOE* (Adjusted for Compliance)	Compliance Group	Compliance* (Adjusted for LOE)
PART-O Total	3 months	0.25 (0.21-0.30) [†]	0%-20% vs ≥50%	-0.02 (-0.12 to 0.09)
			20%-50% vs ≥50%	-0.02 (-0.11 to 0.07)
	9 months	0.26 (0.20-0.32) [†]	0%-20% vs ≥50%	-0.04 (-0.19 to 0.10)
			20%-50% vs ≥50%	-0.02 (-0.12 to 0.09)
PART-O Rasch Total	3 months	4.31 (3.39-5.23) [†]	0%-20% vs ≥50%	-0.82 (-2.29 to 0.65)
			20%-50% vs ≥50%	-0.94 (-2.37 to 0.49)
	9 months	3.57 (2.58-4.56) [†]	0%-20% vs ≥50%	0.08 (-1.86 to 2.03)
			20%-50% vs ≥50%	0.00 (-1.49 to 1.49)
PART-O Social	3 months	0.24 (0.15-0.32) [†]	0%-20% vs ≥50%	-0.03 (-0.22 to 0.15)
			20%-50% vs ≥50%	-0.15 (-0.28 to -0.02)
	9 months	0.21 (0.13-0.28) [†]	0%-20% vs ≥50%	-0.09 (-0.26 to 0.09)
			20%-50% vs ≥50%	-0.06 (-0.18 to 0.06)
PART-O Productivity	3 months	0.29 (0.24-0.34) [†]	0%-20% vs ≥50%	0.02 (-0.11 to 0.15)
			20%-50% vs ≥50%	0.09 (-0.03 to 0.20)
	9 months	0.36 (0.30-0.43) [†]	0%-20% vs ≥50%	0.01 (-0.18 to 0.20)
			20%-50% vs ≥50%	0.01 (-0.14 to 0.17)
PART-O Out and About	3 months	0.23 (0.17-0.29) [†]	0%-20% vs ≥50%	-0.04 (-0.19 to 0.12)
			20%-50% vs ≥50%	-0.01 (-0.13 to 0.12)
	9 months	0.21 (0.14-0.27) [†]	0%-20% vs ≥50%	-0.05 (-0.23 to 0.14)
			20%-50% vs ≥50%	0.02 (-0.11 to 0.15)
FIM Rasch Cognitive	Discharge	11.42 (10.55-12.30) [†]	0%-20% vs ≥50%	1.18 (-0.86 to 3.22)
			20%-50% vs ≥50%	0.38 (-1.29 to 2.06)
	3 months	8.69 (6.87-10.50) [†]	0%-20% vs ≥50%	0.88 (-2.66 to 4.43)
			20%-50% vs ≥50%	-0.94 (-4.06 to 2.18)
	9 months	7.55 (5.56- 9.54) [†]	0%-20% vs ≥50%	1.08 (-2.69 to 4.85)
			20%-50% vs ≥50%	0.63 (-1.91 to 3.16)
FIM Rasch Motor	Discharge	8.52 (7.40-9.63) [†]	0%-20% vs ≥50%	0.81 (-1.05 to 2.66)
			20%-50% vs ≥50%	0.86 (-0.65 to 2.37)
	3 months	11.02 (9.11-12.93) [†]	0%-20% vs ≥50%	1.35 (-2.61 to 5.31)
			20%-50% vs ≥50%	1.85 (-1.01 to 4.70)
	9 months	9.73 (7.34-12.12) [†]	0%-20% vs ≥50%	0.14 (-4.34 to 4.62)
			20%-50% vs ≥50%	-0.35 (-3.23 to 2.53)
Satisfaction with Life	3 months	0.77 (0.09-1.44) [‡]	0%-20% vs ≥50%	0.21 (-1.73 to 2.14)
			20%-50% vs ≥50%	-0.31 (-1.80 to 1.18)
	9 months	1.25 (0.48-2.02) [§]	0%-20% vs ≥50%	-0.42 (-2.63 to 1.78)
			20%-50% vs ≥50%	0.56 (-0.85 to 1.97)
PHQ-9	3 months	1.13 (0.89-1.43)	0%-20% vs ≥50%	0.71 (0.38-1.31)
			20%-50% vs ≥50%	0.65 (0.40-1.05)
	9 months	0.99 (0.80-1.23)	0%-20% vs ≥50%	1.16 (0.66-2.05)
			20%-50% vs ≥50%	0.68 (0.42-1.08)

NOTE. Average adjusted effect, 95% CI.

Abbreviations: PHQ-9, Patient Health Questionnaire-9.

* Mean differences (95% CI) for all outcomes except PHQ-9, which is an odds ratio.

† $P < .001$.‡ $P < .05$.§ $P < .01$.

Productivity at 3 months. While effect modification of LOE remained significant for SWLS at both 3 and 9 months (see [supplemental fig S4](#) and [S5](#)), the post-hoc comparisons at the different ratings of LOE were not significant. For those outcomes for which a significant effect modification was not found, the main effect of compliance was examined. Adjusting for LOE, no significant main effects of compliance were identified ([supplemental table S4](#), available online only at <http://www.archives-pmr.org/>).

For both severity groups, the moderating influence of LOE on compliance's effects was similar across the FIM Cognitive and PART-O outcomes, and generally in the same direction for all

significant post-hoc analysis. As illustrated in [figures 1 to 5](#) (additional figures in [supplemental material](#)), LOE had a stronger positive influence on FIM Cognitive and PART-O outcomes for those with 50% or more of therapy days in compliance, as compared to its influence for those in the 0% to 20% compliance group. In particular for PART-O outcomes, as effort increased in those with 50% or more therapy days in compliance, outcomes improved. For those with few therapy days in compliance (0%-20%) we did not see an effect on outcomes if LOE varied. The effects of LOE on the 20% to 50% compliance group often fell in between the other 2 groups. [Table 3](#) describes the average

Table 3 Subgroup adjusted, significant ($P < .05$) effect modification (mean differences) of LOE on compliance with the 3-Hour Rule, by LOE

Outcome	Compliance Group	LOE: 1*	LOE: 4	LOE: 7
Severe cohort				
PART-O Total Rasch, 9 months	0%-20% vs 50%+	4.34 (-2.38 to 11.06)	-0.33 (-3.02 to 2.37)	-4.99 (-13.64 to 3.66)
	20%-50% vs 50%+	-6.71 (-14.77 to 1.35)	0.05 (-1.55 to 1.65)	6.82 (-0.97 to 14.61)
FIM Rasch Cognitive, 3 months	0%-20% vs 50%+	25.66 (10.63-40.69)	-0.58 (-4.87 to 3.71)	-26.82 (-44.17 to -9.47)
	20%-50% vs 50%+	-1.65 (-17.32 to 14.01)	0.72 (-2.72 to 4.17)	3.1 (-14.42 to 20.63)
Less severe cohort				
PART-O Total, 9 months	0%-20% vs 50%+	0.99 (0.37-1.61)	0.24 (0.06-0.42)	-0.51 (-0.92 to -0.1)
	20%-50% vs 50%+	0.62 (-0.02 to 1.27)	0.15 (-0.03 to 0.33)	-0.32 (-0.72 to 0.08)
PART-O Total Rasch, 9 months	0%-20% vs 50%+	11.71 (4.27-19.15)	3.74 (1.66-5.82)	-4.23 (-9.24 to 0.78)
	20%-50% vs 50%+	7.07 (-0.95 to 15.08)	2.62 (0.45-4.79)	-1.83 (-7.1 to 3.45)
PART-O Out and About, 3 months	0%-20% vs 50%+	1.06 (0.12-2)	0.18 (-0.07 to 0.44)	-0.7 (-1.27 to -0.12)
	20%-50% vs 50%+	0.36 (-0.5 to 1.23)	0.05 (-0.19 to 0.28)	-0.27 (-0.81 to 0.27)
PART-O Out and About, 9 months	0%-20% vs 50%+	1.12 (0.39-1.86)	0.31 (0.1-0.52)	-0.51 (-0.99 to -0.02)
	20%-50% vs 50%+	0.9 (0.15-1.65)	0.27 (0.06-0.47)	-0.37 (-0.86 to 0.13)
PART-O Productivity, 3 months	0%-20% vs 50%+	1.17 (0.28-2.07)	0.27 (0.07-0.48)	-0.63 (-1.28 to 0.03)
	20%-50% vs 50%+	0.7 (-0.21 to 1.61)	0.26 (0.06-0.46)	-0.18 (-0.84 to 0.48)
PART-O Social, 9 months	0%-20% vs 50%+	1.37 (0.57-2.17)	0.28 (0.05-0.51)	-0.81 (-1.32 to -0.3)
	20%-50% vs 50%+	0.81 (-0.06 to 1.69)	0.13 (-0.12 to 0.38)	-0.56 (-1.08 to -0.03)
FIM Rasch Cognitive, discharge	0%-20% vs 50%+	12.56 (2.07-23.05)	3.68 (1.06-6.3)	-5.21 (-12.26-1.85)
	20%-50% vs 50%+	-0.55 (-12.12 to 11.01)	0.51 (-2.11 to 3.12)	1.57 (-6.35 to 9.48)
Satisfaction with Life, 9 months	0%-20% vs 50%+	8.66 (-2.64 to 19.95)	1.98 (-1.23 to 5.19)	-4.7 (-11.16 to 1.77)
	20%-50% vs 50%+	-0.97 (-12.79 to 10.84)	1.04 (-2.2 to 4.27)	3.05 (-3.54 to 9.63)
Satisfaction with Life, 3 months	0%-20% vs 50%+	7.06 (-1.53 to 15.65)	1.27 (-1.43 to 3.97)	-4.52 (-9.75 to 0.7)
	20%-50% vs 50%+	-5.49 (-14.08 to 3.1)	-1.41 (-4.1 to 1.28)	2.68 (-2.04 to 7.39)

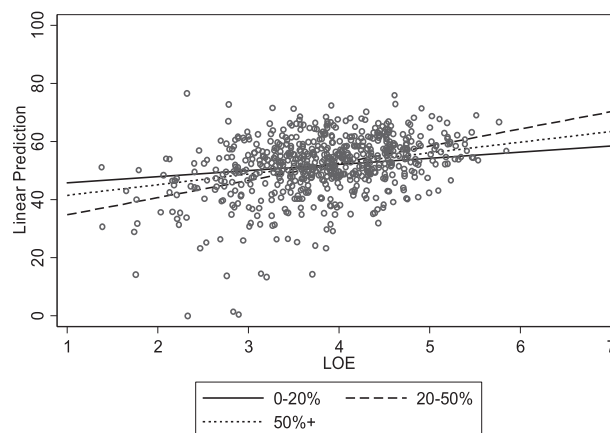
NOTE. Average adjusted effect (95% CI).

* LOE = 2,3,5,6 are excluded from table for readability; see figures for all values.

difference in scores, relative to 50%+ compliance, for outcomes across LOE. To determine if the size of the effects differed based on initial level of disability, we evaluated the overlap of CIs for the effects. The CIs of the effects overlapped substantially, suggesting that the effects of compliance and LOE on outcomes were not different between the severity groups.

Discussion

Compliance with the 3-Hour Rule did not have a significant effect on outcomes in this sample of patients with TBI from IRF. However, LOE was significantly associated with the majority of the outcomes up to 9 months postdischarge, including community participation, functional independence, and life satisfaction, but not likelihood of depression. Our a priori hypothesis that the effect of 3-Hour Rule compliance on outcomes is moderated by the LOE that patients were able to expend in treatment was not supported

**Fig 1** Severe subgroup: interaction plot for PART-O total Rasch at 9 months (adjusted model).

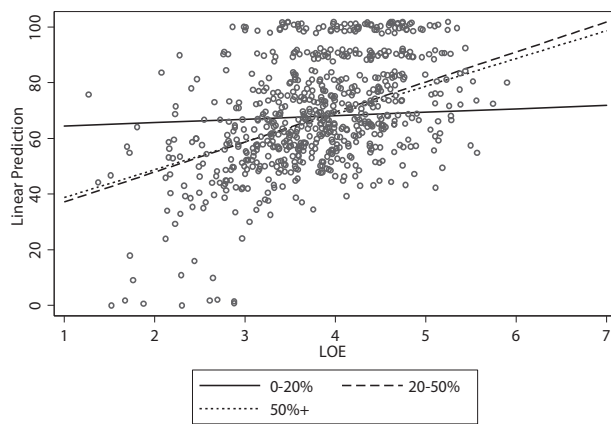


Fig 2 Severe subgroup: interaction plot for FIM Cognitive Rasch at 3 months (adjusted model).

when the full cohort was used in the analysis. However, when the sample was stratified by initial severity of disability, there was a significant interaction between 3-Hour Rule compliance and LOE with regard to outcomes for patients with less severe disability, and minimally for those with more severe disability. LOE had a stronger effect on the outcomes of those participants with 50% or more days in compliance than its effect on those with 0% to 20% days in compliance. Participants with lower LOE did poorly when provided with 3+ hours of therapy for more than half of their therapy days in comparison to patients who received 3+ hours of therapy during a small proportion of their rehabilitation days. Matching intensity of therapy, as measured by total time, to the patient's LOE appears to produce optimum results.

The results of this study do not support the mandate of 3 hours of therapy for all patients at all times during the inpatient stay. Rather, time in therapy needs to be tailored for each patient based on LOE, in order to maximize response to rehabilitation. This patient-centered approach is a smarter use of resources. Unfortunately, short of a reversal of a federal regulation that has been in place for over 35 years, providers will need to focus on other solutions to adapt therapy time to the patient's needs (eg, brief frequent therapy dosing across the day, increased rest breaks, etc) with the goal of finding the sweet spot between time and effort that maximizes patients' outcomes. Providers will also need to

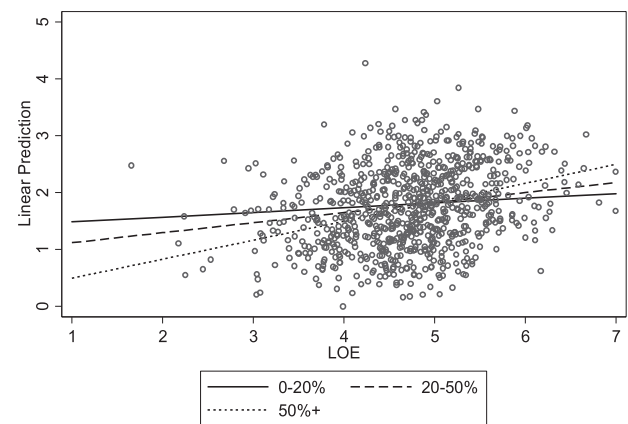


Fig 4 Less severe subgroup: interaction plot for PART-0 total at 9 months (adjusted model).

identify unique features within each individual (ie, person-focused) to enhance LOE during therapy.

Some people might argue that persons who are only able to expend low levels of effort should be denied admission to IRFs since they do not benefit from the mandated 3 hours of therapy. This contention was not tested in our study, and we would argue against this interpretation. LOE as measured in this study was collected following admission to IRF and within the context of each therapy session. The findings speak more to the need to change the therapeutic environment to match patients' needs than to denying access to IRF-level of care.

This study focused on identifying what has the greatest effect on patient hospital discharge outcomes and longer-term life outcomes. While time in therapy is likely to continue to be debated as a potential active ingredient in inpatient rehabilitation, the current finding of the importance of LOE within sessions adds to the growing body of literature indicating that time is not the only ingredient to positively affect outcomes. Other studies have found that, for instance, function-focused activities in rehabilitation are more effective than impairment-focused activities.⁹ The accumulating evidence confirms that rehabilitation is a complex process and cannot be defined simply as an aggregate of time.²⁵ Future research must continue to focus on identifying ingredients that promote the greatest benefits for patients.

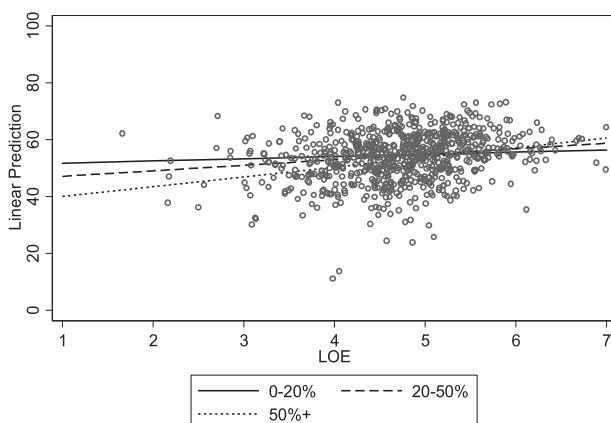


Fig 3 Less severe subgroup: interaction plot for PART-0 total Rasch at 9 months (adjusted model).

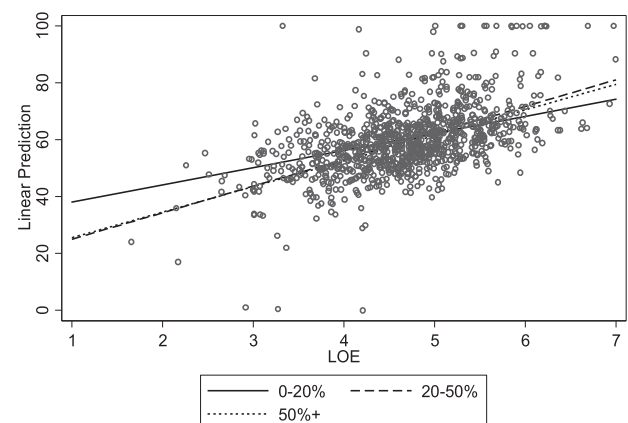


Fig 5 Less severe subgroup: interaction plot for FIM Cognitive Rasch at discharge (adjusted model).

Study limitations

We were not able to capture the reasons patients did not receive 3 hours of therapy, which could better inform the interpretation of results. The current study based causal inference on propensity score analysis of observational data, rather than on the more widely accepted randomized controlled trial. We cannot be certain that all confounders were measured. In addition, while we achieved excellent balance of the confounders across different levels of exposure to the treatment (compliance) for the full cohort, we were not able to achieve our preset criterion for a large number of confounders when we stratified the sample, particularly in the severe subgroup. Adjusting the models by the unbalanced covariates increases our confidence in the results, but interpretation still should be made cautiously. Further, while we use a comprehensive model for multiple imputation of missing outcomes, which included all covariates believed to potentially be related to outcomes, expected interactions and observed outcomes to impute missing outcomes over time, there is no test to ensure that our data was not missing due to some unobserved variables.

The associations found between LOE and the outcomes should also be interpreted carefully because the propensity score methods were used to balance the confounders on 3-Hour Rule compliance, not on LOE. Causal inferences can only be made relative to compliance, not LOE. The association between LOE and outcomes could be reflective of underlying factors, such as tenaciousness, that can affect performance in both rehabilitation and in the community. However, this possibility should not discount the need to adapt rehabilitation to the individual's ability to expend effort, whether this is a reflection of a temporary state or an enduring trait.

Conclusions

Engagement in therapy was found to be more important than the amount of time in therapy for optimizing outcomes, providing evidence for a need to reconsider the 3-Hour Rule. Individualizing the amount of treatment per day to be in line with the person's ability to engage and fully participate in therapy will likely yield better outcomes.

Suppliers

- a. SAS v9.3 38 software; SAS Institute, Inc.
- b. Stata version 14.0 39 software; StataCorp.

Keywords

Brain injuries, traumatic; Health services research; Occupational therapy; Physical therapy specialty; Recreation therapy; Rehabilitation; Speech therapy

Corresponding author

Jennifer Bogner, PhD, 480 Medical Center Drive, Columbus, OH 43210. E-mail address: bogner.1@osu.edu.

Acknowledgments

We thank the stakeholders on the research team, including Carolyn Rocchio, Marvel Vena, Candace Gustafson, RN, CBIST, Michelle Maust, BSN, and Irene Ziaya, LCSW, MBA.

References

1. Centers for Medicare and Medicaid Medicare Learning Network. Inpatient rehabilitation facility (IRF) medical review changes. MLN Matters 2017;SE17036.
2. Johnston MV, Miller LS. Cost-effectiveness of the Medicare three-hour regulation. *Arch Phys Med Rehabil* 1986;67:581-5.
3. Turner-Stokes L, Pick A, Nair A, Disler PB, Wade DT. Multidisciplinary rehabilitation for acquired brain injury in adults of working age. *Cochrane Database Syst Rev* 2015;CD004170.
4. Konigs M, Beurskens EA, Snoep L, Scherder EJ, Oosterlaan J. Effects of timing and intensity of neurorehabilitation on functional outcome after traumatic brain injury: a systematic review and meta-analysis. *Arch Phys Med Rehabil* 2018;99:1149-1159.e1.
5. Wang H, Camicia M, Terdiman J, Mannava MK, Sidney S, Sandel ME. Daily treatment time and functional gains of stroke patients during inpatient rehabilitation. *PM R* 2013;5:122-8.
6. Nagai S, Sonoda S, Miyai I, et al. Relationship between the intensity of stroke rehabilitation and outcome: a survey conducted by the Kaifukuki rehabilitation ward association in Japan (second report). *Jpn J Compr Rehabil Sci* 2011;2:77-81.
7. Horn SD, Corrigan JD, Beaulieu CL, et al. Traumatic brain injury patient, injury, therapy, and ancillary treatments associated with outcomes at discharge and 9 months postdischarge. *Arch Phys Med Rehabil* 2015;96(8 Suppl):S304-29.
8. Pegg P, Auerbach S, Seel R, Buenaver L, Kiesler D, Plybon L. The impact of patient-center information on patients' treatment satisfaction and outcomes in traumatic brain injury rehabilitation. *Rehabil Psychol* 2005;50:366-74.
9. Bode RK, Heinemann AW, Semik P, Mallinson T. Relative importance of rehabilitation therapy characteristics on functional outcomes for persons with stroke. *Stroke* 2004;35:2537-42.
10. Seel RT, Corrigan JD, Dijkers MP, et al. Patient effort in traumatic brain injury inpatient rehabilitation: course and associations with age, brain injury severity, and time postinjury. *Arch Phys Med Rehabil* 2015;96(8 Suppl):S235-44.
11. Horn SD, Corrigan JD, Bogner J, et al. Traumatic Brain Injury-Practice Based Evidence study: design and patients, centers, treatments, and outcomes. *Arch Phys Med Rehabil* 2015;96(8 Suppl):S178-196.e15.
12. Seel RT, Barrett RS, Beaulieu CL, et al. Institutional variation in traumatic brain injury acute rehabilitation practice. *Arch Phys Med Rehabil* 2015;96(8 Suppl):S197-208.
13. Heinemann AW, Linacre JM, Wright BD, Hamilton BB, Granger C. Relationships between impairment and physical disability as measured by the Functional Independence Measure. *Arch Phys Med Rehabil* 1993;74:566-73.
14. Whiteneck GG, Dijkers MP, Heinemann AW, et al. Development of the participation assessment with recombined tools-objective for use after traumatic brain injury. *Arch Phys Med Rehabil* 2011;92:542-51.
15. Bogner JA, Whiteneck GG, Corrigan JD, Lai JS, Dijkers MP, Heinemann AW. Comparison of scoring methods for the participation assessment with recombined tools-objective. *Arch Phys Med Rehabil* 2011;92:552-63.
16. Malec JF, Whiteneck GG, Bogner JA. Another look at the PART-O using the Traumatic Brain Injury Model Systems national database: Scoring to optimize psychometrics. *Arch Phys Med Rehabil* 2016;97:211-7.
17. Linacre JM, Heinemann AW, Wright BD, Granger CV, Hamilton BB. The structure and stability of the functional independence measure. *Arch Phys Med Rehabil* 1994;75:127-32.

18. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. *J Gen Intern Med* 2001;16: 606-13.
19. Fann JR, Bombardier CH, Dikmen S, et al. Validity of the Patient Health Questionnaire-9 in assessing depression following traumatic brain injury. *J Head Trauma Rehabil* 2005;20:501-11.
20. Diener E, Emmons RA, Larsen RJ, Griffin S. The satisfaction with life scale. *J Pers Assess* 1985;49:71-5.
21. Hamilton BB, Laughlin JA, Fiedler RC, Granger CV. Interrater reliability of the 7-level Functional Independence Measure (FIM). *Scand J Rehabil Med* 1994;26:115-9.
22. Pavot W, Diener E, Colvin CR, Sandvik E. Further validation of the satisfaction with life scale: Evidence for the cross-method convergence of well-being measures. *J Pers Assess* 1991;57: 149-61.
23. Williams RT, Heinemann AW, Neumann HD, et al. Evaluating the psychometric properties and responsiveness to change of 3 depression measures in a sample of persons with traumatic spinal cord injury and major depressive disorder. *Arch Phys Med Rehabil* 2016;97:929-37.
24. Austin PC, Stuart EA. Moving towards best practice when using inverse probability of treatment weighting (IPTW) using the propensity score to estimate causal treatment effects in observational studies. *Stat Med* 2015;34:3661-79.
25. Whyte J, Hart T. It's more than a black box; it's a Russian doll: defining rehabilitation treatments. *Am J Phys Med Rehabil* 2003;82: 639-52.