## **Supplementary Online Content**

Perni S, Rooney MK, Horowitz DP. Assessment of use, specificity, and readability of written clinical informed consent forms for patients with cancer undergoing radiotherapy. Published online May 2, 2019. *JAMA*. doi:10.1001/jamaoncol.2019.0260

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This supplementary material has been provided by the authors to give readers additional information about their work.

## eMethods 1. Questions sent to departmental leaders

1) Does your facility have a written radiation informed consent form that is used for routine clinical radiation treatment (outside the context of a clinical trial)?

If so, would you please send us a copy of this form for us to use as the primary data for our study? (We plan to perform detailed content analysis of the forms from many institutions to help ascertain best practices.)

2) Do you have different templates depending on the site being treated (e.g., a form used for breast cancer treatment, a form used for brain irradiation, etc.)?

If so, would you please also send us copies of the forms you use when a patient is being treated to the whole breast and also when a patient is being treated to the whole brain?

- 3) Are these forms provided for the patient to take home for review prior to obtaining consent?
- 4) Are these forms provided for the patient to take home for review after consent is obtained?

## eMethods 2. Description of readability indices

Readability Score	Description or calculation formula
Degrees of Reading Power (Grade Equivalent) (DRP(GE)) <sup>1</sup>	-
Flesch-Kincaid (FK) <sup>2</sup>	FK = (0.39 x ASL) + (11.8 x ASW) - 15.59, where ASL = average sentence length and ASW = average number of syllables per word
FORd, CAylor, STich index (FORCAST) <sup>3</sup>	FORCAST = 20 – (N/10), where N is number of monosyllabic words in a random 150 word sample
Fry⁴	Fry score is calculated by plotting the number of syllables per 100 words on the horizontal axis (x-axis), and the average number of sentences per 100 words on the vertical axis (y-axis). The region this point falls is an estimation of grade level.
Gunning Fog (GF) <sup>5</sup>	GF= 0.4 (ASL + PHW), where ASL = average sentence length and PHW = percentage hard words, defined as words with 3+ syllables that are NOT (i) proper nouns, (ii) combinations of easy words or hyphenated words, or (iii) two-syllable verbs made into three with -es and -ed ending
Raygor Estimate <sup>6</sup>	Raygor estimate is calculated by plotting the number of 6+ character words per 100 words on the horizontal axis (x-axis), and average number of sentence per 100 words on the vertical axis (y-axis). The region this point falls is an estimation of grade level.
Simple Measure Of Gobbledygook (SMOG) <sup>7</sup>	SMOG = sqrt (# of 3+ syllable words) +3 in a 30 sentence sample of text

eTable 1. Comparison of departments offering and not offering radiotherapy consent forms in the survey

	Departments not offering forms			Departments offering forms		P value	
		<u>To</u>	tal Programs:	88*			
	Count	(%)		Count	(%)		
	31	35		57	65		
		Resid	ency Program	Size**	ul		
Mean	8.4			9.8		0.12	
Range	24 (4 to 28)			26 (4 to 30)			
		Resea	rch Output Rai	nking**	•		
Mean	44.8			43.0		0.38	
Range	2 to 86			1 to 94			
			Location**		•	0.059	
South	9	29		14	25		
Northeast	9	29		17	30		
West	10	32		8	14		
Midwest	3	10		18	32		
	Rural or Urban Training Site**						
Rural	2	6		2	4		
Urban	29	94		55	96		
	Large Public University**						
Yes	11	35		22	39		
No	20	65		35	61		

Differences in continuous variables between groups were assessed with one-way t-tests; differences in categorical variables between groups were measured with chi-square tests.

<sup>\*89</sup> department were surveyed in total. One department was not included in the doximity.com residency navigator and was thus excluded from this analysis (that department did not provide consent forms).

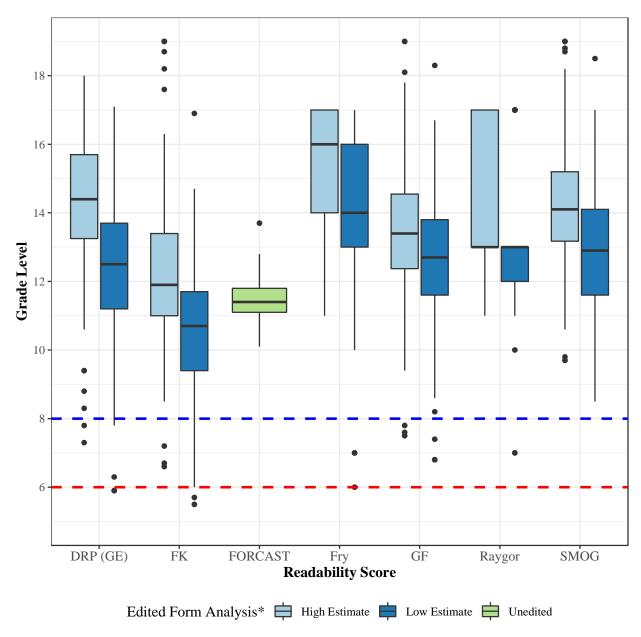
<sup>\*\*</sup>Department characteristics determined according to doximity com residency navigator program descriptions

eTable 2. Statistics describing estimated readability of cancer radiotherapy consent forms in U.S. academic centers by seven readability measures

	Test	Minimu m	Maximu m	Rang e	Mea n	Number of forms at sixth grade readabilit y level or below	%	Number of forms at eighth grade readabilit y level or below	%
	DRP (GE)	5.9	17.1	11.2	12.3	3	2. 7	4	3. 5
	FK	5.5	16.9	11.4	10.6	4	3. 5	9	8
Low Estimat	Fry	6	17	11	14.2	1	1. 6	3	4. 9
е	GF	6.8	18.3	11.5	12.6	0	0	4	3. 5
	Raygor Estimate	7	17	10	13.2	0	0	1	1. 7
	SMOG	8.5	18.5	10	12.9	0	0	0	0
	DRP (GE)	7.3	18	10.7	14.3	0	0	3	2.
	FK	6.6	19	12.4	12.3	0	0	3	2. 7
High Estimat	Fry	11	17	6	15.2	0	0	0	0
e	GF	7.5	19	11.5	13.4	0	0	3	2. 7
	Raygor Estimate	11	17	6	14.3	0	0	0	0
	SMOG	9.7	19	9.3	14.3	0	0	0	0
	FORCAS T	10.3	13.6	3.3	11.5	0	0	0	0

DRP (GE) = Degrees of Reading Power (Grade Equivalent); FK = Flesch-Kincaid; FORCAST = FORd, CAylor, STich; GF = Gunning Fog; SMOG = Simple Measure Of Gobbledygook

eFigure 1. Readability of consent forms for cancer radiotherapy in U.S. academic centers as measured by seven readability indices, using paired high and low estimates for each index

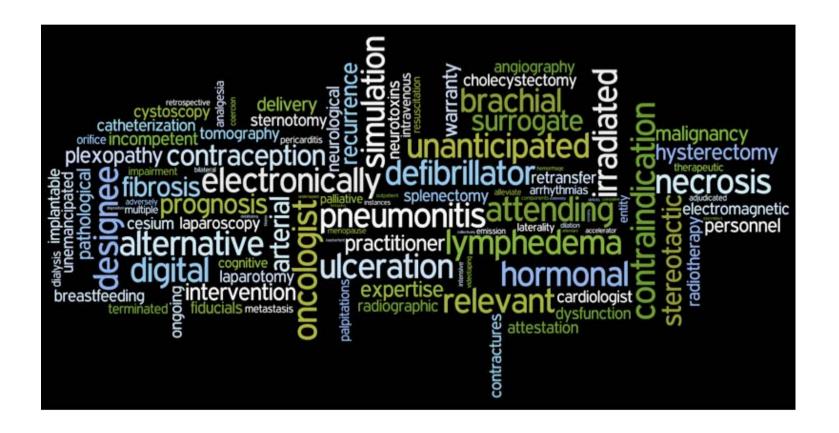


Boxes represent the median and interquartile range (IQR) for each distribution, with the lower and upper box limits defined by the 25<sup>th</sup> and 75<sup>th</sup> percentile, respectively. The median is represented by the line across each box. The upper and lower whiskers extend to the greatest and least datum within 1.5\*IQR above and below the upper and lower quartile, respectively. Any data points outside of this range are defined as outliers, and displayed as dots. Whisker end bars are not included in this plot to improve the clarity of data presentation. Maximum reported grade levels for included readability scores can range up to grade 19 (equivalent to a doctoral degree level of education) for some scores. Reported grade levels higher than grade 12 represent collegiate levels of education and above. Current recommendations from the National Cancer Institute and National Institutes of Health state that consent forms for patients should be at the 8<sup>th</sup> grade readability level or below (blue horizontal dashed line). Our patients should be at the 8<sup>th</sup> grade readability level or below (red horizontal dashed line). Our patients should be at the 8<sup>th</sup> grade readability level or below (red horizontal dashed line).

\*Documents were manually edited for high and low estimation of scores dependent on sentence length (for all readability scores except for FORCAST). In the high estimate, forms were altered so all lists were treated as one sentence with items separated by a comma. In the low estimate, forms were edited so all list items were treated as independent sentences separated by a period.

DRP (GE) = Degrees of Reading Power (Grade Equivalent); FK = Flesch-Kincaid; FORCAST = FORd, CAylor, STich; GF = Gunning Fog; SMOG = Simple Measure Of Gobbledygook

eFigure 2. Word cloud of commonly used difficult words



eTable 3. Commonly used difficult words with recommended alternatives

Difficult Word*	Number of forms using word (%)	The Living Word Vocabulary grade level	Percent of students at grade level who understand the word meaning (%)	Recommended replacement?** (yes/no)	Recommended alternatives **
alternative(-ate)	62 (54%)	12	81	yes	other, possible
oncologist(-y)	35 (31%)	Unlisted	NA	yes	cancer doctor
simulation	24 (21%)	12	61	yes	practice setup used to plan your treatment
attending (physician)	21 (19%)	Unlisted	NA	yes	senior doctor
(contra)indicated(- ions)	18 (16%)	Unlisted	NA	yes	reasons to/not to do something
intervention(s,-al)	17 (15%)	12	67	yes	treatment
recurrence(s,-t)	17 (15%)	12	71	yes	comes back
unanticipated	16 (14%)	Unlisted	NA	yes	not expected
practitioner	16 (14%)	12	89	yes	medical professional
designee(s)	15 (13%)	Unlisted	NA	yes	person you pick
ulceration(s)	15 (13%)	Unlisted	NA	yes	wound
malignancy(-ies)	15 (13%)	12	71	yes	cancer
warranty(-ies)	15 (13%)	12	60	yes	guarantee
necrosis	13 (12%)	13	46	yes	death of body cells
personnel	14 (12%)	12	84	yes	people, professionals
(in)competent(-ce)	13 (12%)	12	73	yes	qualified, qualifications
neurologic(al)	13 (12%)	12	74	yes	related to the brain or nerves
implanted(-able)	12 (11%)	12	67	yes	something put in
arterial(-y,-ies)	10 (9%)	13	54	yes	related to the blood or blood carrying system

prognosis(-tic)	10 (9%)	13	60	yes	future prediction
Difficult Word*	Number of forms using word (%)	The Living Word Vocabulary grade level	Percent of students at grade level who understand the word meaning (%)	Recommended replacement?** (yes/no)	Recommended alternatives **
intravenous(ly)	10 (9%)	12	83	yes	into veins
terminate(d,-ion)	10 (9%)	12	80	yes	end, stop
defibrillator	9 (8%)	Unlisted	NA	yes	device to shock the heart
lymph(edema)	9 (8%)	Unlisted	NA	yes	swelling
impairment	8 (7%)	12	58	yes	disability
laterality	8 (7%)	12	76	yes	to the side
multiple	8 (7%)	12	70	yes	more than one
therapeutic	8 (7%)	12	73	yes	healing, treating, curing
pneumonitis	8 (7%)	Unlisted	NA	yes	damaged or irritated lung
contraception(-ve)	7 (6%)	16	72	yes	something to prevent pregnancy
surrogate	7 (6%)	16	42	yes	fill-in, substitute, act in place of
pathologist(-al)	7 (6%)	13	65	yes	doctors who specialize in looking under the microscope
(myo)pericarditis(- ium)	7 (6%)	12	77	yes	inflammation of the heart or heart sac
brachial	6 (5%)	Unlisted	NA	yes	related to the arm
attestation	6 (5%)	13	73	yes	proof, evidence
catheter(ization)	6 (5%)	13	49	yes	urine tube
radiology(-ic,- graphic)	6 (5%)	13	32	yes	related to x rays or medical scans
adversely	6 (5%)	12	70	yes	negatively
alleviate	6 (5%)	12	79	yes	to make better
fibrosis	5 (4%)	Unlisted	NA	yes	hardening
stereotactic	5 (4%)	Unlisted	NA	yes	highly accurate aiming and body position

hysterectomy	4 (4%)	Unlisted	NA	yes	surgery to remove the uterus
plexopathy	4 (4%)	Unlisted	NA	yes	damage to the nerves
Difficult Word*	Number of forms using word (%)	The Living Word Vocabulary grade level	Percent of students at grade level who understand the word meaning (%)	Recommended replacement?** (yes/no)	Recommended alternatives **
cognitive(-ion)	5 (4%)	13	62	yes	related to thinking ability
palpitations	5 (4%)	13	69	yes	abnormal feeling of heart beat
metastasis(-ic)	4 (4%)	13	63	yes	spread of the cancer
resuscitate(d,-ion,- ive)	4 (4%)	13	71	yes	bring back to health, restore
accelerator	5 (4%)	12	61	yes	machine to create high energy beams
bilateral	5 (4%)	12	77	yes	both sides
dilation(-ed)	5 (4%)	12	67	yes	make bigger
intensive	5 (4%)	12	69	yes	extreme, severe
components	4 (4%)	12	81	yes	parts
hemorrhage	4 (4%)	12	79	yes	bleed
angiography	3 (3%)	Unlisted	NA	yes	procedure to view the blood vessels
cardiologist	3 (3%)	Unlisted	NA	yes	heart doctor
cesium	3 (3%)	Unlisted	NA	yes	radiation source
cholecystectomy	3 (3%)	Unlisted	NA	yes	surgery to remove the gallbladder
contracture(s)	3 (3%)	Unlisted	NA	yes	permanent shortening
cystoscopy	3 (3%)	Unlisted	NA	yes	procedure to look into the bladder
dysfunction	3 (3%)	Unlisted	NA	yes	problems with
electromagnetic	3 (3%)	Unlisted	NA	yes	high energy beam
fiducials	3 (3%)	Unlisted	NA	yes	markers
laparoscopy(-ic)	3 (3%)	Unlisted	NA	yes	procedure to look into the abdomen with a small camera
laparotomy	3 (3%)	Unlisted	NA	yes	surgery to open the abdomen

neurotoxin(s)	3 (3%)	Unlisted	NA	yes	substance that hurts the nerves
retransfer	3 (3%)	Unlisted	NA	yes	transfer again
Difficult Word*	Number of forms using word (%)	The Living Word Vocabulary grade level	Percent of students at grade level who understand the word meaning (%)	Recommended replacement?** (yes/no)	Recommended alternatives **
sternotomy	3 (3%)	Unlisted	NA	yes	surgery to open the chest near the breastbone
tomography	3 (3%)	Unlisted	NA	yes	mapping
unemancipated	3 (3%)	Unlisted	NA	yes	minor who is under legal supervision of parents or guardians
analgesia	3 (3%)	16	73	yes	pain management
arrhythmia(s)	3 (3%)	16	46	yes	problems with heart beat
dialysis	3 (3%)	16	51	yes	procedure to clean the blood
entity	3 (3%)	16	56	yes	person
orifice	3 (3%)	16	63	yes	opening, hole
palliative(-ion)	3 (3%)	16	60	yes	improve symptoms
adjudicated	3 (3%)	13	61	yes	judged, declared
coercion	3 (3%)	13	52	yes	pressured or forced to do something
emission	3 (3%)	13	72	yes	release
retrospective	3 (3%)	13	75	yes	looking back
attendant	3 (3%)	12	78	yes	witness, person present
biopsy	3 (3%)	12	80	yes	tissue sample
collectively	3 (3%)	12	70	yes	together
cumulative	3 (3%)	12	82	yes	sum, total
debilitation(-ing)	3 (3%)	12	55	yes	weakness, weakening
deficit(s)	3 (3%)	12	72	yes	problem with
disposition	3 (3%)	12	57	yes	arrangement, placement
extremity(-ies)	3 (3%)	12	73	yes	arms and legs

foregoing	3 (3%)	12	67	yes	going without
inadvertent	3 (3%)	12	68	yes	not intended
Difficult Word*	Number of forms using word (%)	The Living Word Vocabulary grade level	Percent of students at grade level who understand the word meaning (%)	Recommended replacement?** (yes/no)	Recommended alternatives **
ionizing	3 (3%)	12	78	yes	energized
undersigned	3 (3%)	12	83	yes	person signing
irradiated(-ion)	20 (18%)	13	45	no	NA
delivery	14 (12%)	12	63	no	NA
radiotherapy	13 (12%)	12	50	no	NA
relevant	10 (9%)	16	71	no	NA
hormonal	8 (7%)	Unlisted	NA	no	NA
digital	7 (6%)	Unlisted	NA	no	NA
electronic(ally)	7 (6%)	Unlisted	NA	no	NA
menopause(-al)	6 (5%)	12	71	no	NA
expertise	4 (4%)	Unlisted	NA	no	NA
instances	5 (4%)	12	65	no	NA
videotaping(s)	5 (4%)	12	65	no	NA
outpatient	4 (4%)	12	60	no	NA
breastfeeding	3 (3%)	Unlisted	NA	no	NA
ongoing	3 (3%)	Unlisted	NA	no	NA

<sup>\*</sup>Inclusion criteria for a "commonly used difficult word": 1) Any word with ≥3 syllables that was used at least once in ≥3 forms and; 2) was either unlisted or categorized as ≥12<sup>th</sup> grade readability level by The Living Word Vocabulary list
\*\*Words meeting inclusion criteria were individually reviewed by the authors and consensus recommendations were developed for words warranting replacement

NA = Not applicable

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