

# Low Quality and Lack of Clarity of Current Informed Consent Forms in Cardiology

## How to Improve Them

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Guidelines on informed consent for clinical practice exhort physicians to use standard plain language to enhance patient comprehension and facilitate shared decision making. The aim of this study was to assess and improve quality and readability of current informed consent forms used in cardiology. We evaluated the currently used informed consent forms, previously written in Italian and English, of 7 common imaging examinations, according to the recommendations of scientific societies. For each text, we also developed a revised informed consent form according to reference standards, including Federal Plain Language guidelines. Regarding readability scores, we analyzed each text (standard and revised) with Flesch-Kincaid (F-K) grade level (higher numbers indicating harder-to-read text) and the Italian language-tailored Gulpease level (from 0 [difficult] to 100 [easy]). Overall quality and readability was poor for both the original English and Italian versions, and readability was improved with the revised form, with higher readability evidenced by changes in both F-K grade level (standard  $10.2 \pm 2.37\%$  vs. revised  $6.5 \pm 0.41\%$ ;  $p < 0.001$ ) for English and Gulpease (standard  $45.7 \pm 2\%$  vs. revised  $84.09 \pm 2.98\%$ ;  $p < 0.0001$ ) for Italian. In conclusion, current informed consent forms are complex, incomplete, and unreadable for the average patient. Substantial quality improvement and higher readability scores can be achieved with revised forms that explicitly discuss risks and are prepared following standard recommendations of plain writing.

Guidelines on informed consent urge physicians to provide patients with all of the relevant information they need to participate in making specific and well-considered choices about their health (1–3). Physicians are responsible for providing patients with all the information on risks, bene-

fits, and alternatives that a “capable patient” would consider significant in making a treatment decision (4,5). There is strong evidence for the effectiveness of written (and audiovisual) materials in supporting decision making by improving both patient knowledge and realistic expectations of the benefits and harm of the treatment. Guidelines also recommend the use of plain language in written leaflets and informed consent forms to enhance comprehension and facilitate shared decision making (6–10). Unfortunately, for common diagnostic (11) and therapeutic cardiological procedures (12), patients believe that the risk will be lower and the benefits will be greater than studies have shown. The aim of the present study was to assess and improve the quality and readabil-

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ity of current informed consent forms used in cardiology. We undertook a 2-stage project. As a first step, we performed a quality analysis of a sample of current leaflets developed for informed consent purposes on the basis of selected reference standards. As a second step, we developed revised informed consent forms validated by an expert panel, consisting of a legal physician, a lawyer, a computational linguistics expert, clinicians, a communication expert, and a patient advocacy organization member.

The study was approved by the Pisa ethical committee as a part (workpackage 5) of the SUIT-Heart (Stop Useless Ionizing Testing in Heart Disease) study on October 1, 2010. For our purposes, an "informed consent form" is intended as a detailed information leaflet about a treatment/intervention proposed for a specific disease/condition containing alternative options and their possible outcomes, useful advice, instructions, and a consent form to be signed by both patient and physician. The main aim of the informed consent form is not to prevent medical liability but to support (not substitute) the physician/patient dialogue and relationship, facilitating a voluntary, informed, and aware expression of the patient's will.

**Informed consent form evaluation.** We evaluated the informed consent forms currently used in an Italian tertiary care and research center (Pisa CNR-FTGM Regione Toscana) for 7 common examinations and previously composed according to the recommendations of scientific societies. The 7 procedures included coronary angiography (CA), percutaneous coronary intervention (PCI), myocardial perfusion imaging (MPI), cardiac positron emission tomography (PET), cardiac computed tomography (CCT), cardiac radiofrequency ablation (CRA), and stress echocardiography (SE). We also analyzed the same sample of consent forms in English, downloaded from international websites: New York University Medical Center, New York, New York,

for catheter ablation; Kaiser Permanente Santa Teresa Community Hospital, San Jose, California, for CCT; Trafford Healthcare National Health System Trust, Manchester, United Kingdom, for SE; Radiologyinfo (13) for cardiac PET; Cedars-Sinai Medical Center, Los Angeles, California, for MPI; Addenbroke's Hospital of Cambridge University, United Kingdom, for CA; and Golden Jubilee National Hospital of National Health System for Sutherland, Glasgow, United Kingdom, for PCI.

**Reference standards.** Quality analysis was performed based on a set of quality criteria freely adapted from the International Patient Decision Aids Standards Collaboration checklist and Coulter's recommendations (14,15). We adopted 3 clusters of quality criteria: 1) content and its organization (relevant information such as features of the proposed procedure, risks, benefits, alternatives and their relative risks and benefits, potential harm from not undergoing the procedure, instructions and frequently asked questions topic organization, and adequate risk communication strategies); 2) text construction and layout (readability scores, active voice, length of sentences, paragraphs and words, font size, typestyle and appropriate spacing, highlights of key points with bold, headings and subheadings, clearly labeled pictures and graphs); and 3) development process (Table 1). For risk communication principles and methods, we referred to the National Research Council publication (16) and the Nuclear Regulatory Commission (17).

Regarding readability scores, health education materials are recommended to be written at no higher than a 5th Flesch-Kincaid grade reading level (18,19) or at an 8th grade level according to Smog or Fry scores (10). Even individuals with higher reading levels have been found to prefer information that is written at lower levels because it is easier to comprehend and takes less time to read (20). For each test, we also developed a

revised informed consent form according to reference standards including Federal Plain Language guidelines (7).

The readability score of each informed consent document (standard and revised) was estimated using different readability indexes based on text statistics analysis. The most widely accepted readability indexes are based on text statistics analysis and are modeled using linear regression techniques applied to large reference corpora. Given a new text document, such indexes provide an estimate of the minimum grade level that is required for the reader to correctly understand that text: the Flesch-Kincaid approach is based on navy training manuals with high numbers indicating harder to read texts; the Gunning Fog approach specifically takes into account complex words; the Coleman-Liau approach is based on text; the Smog index is particularly used for checking health messages; and the Automated Readability Index is based on text, and like the Coleman-Liau, takes into account characters rather than syllables to produce the result. For all of these indexes, best applied to the English language, higher values indicate harder to read texts. The Italian informed consent documents were also analyzed by means of the Italian language-tailored Gulpease readability index, developed in 1982 by the Gruppo Universitario Linguistico Pedagogico at the University of Rome, in collaboration with the Italian section of IBM (21). With this index, best applied to Italian language, lower values indicate harder to read texts. In general, all of the above-mentioned indexes use distributional parameters (e.g., average number of words per sentence, average length of sentences, number of syllables per word, etc.) to derive an index for text readability. They do not take into account less quantifiable factors such as structural complexity, grammatical correctness, or meaning. Thus, there is no guarantee that a text which is judged easy to understand by a readability

**Table 1. Quality Items and Evaluation of the Consent Form for CCT Before and After Text Simplification**

Quality Criteria	Before Text Simplification		After Text Simplification	
	Yes	No	Yes	No
<b>Development</b>				
Information needs were assessed by means of patient interviews, focus groups, or at least literature review	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Informed consent forms were validated by a panel of experts		<input type="checkbox"/>		<input type="checkbox"/>
Informed consent forms were field-tested with patients	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<b>Features</b>				
Multicultural approach and usability	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	
Informed consent forms are available in various languages	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Informed consent forms are written in plain, not jargon, style	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Informed consent forms provide a frequently asked questions topic organization	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Text readability adheres to international standards	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
The font used in the text has serifs and font size is at least 12 point	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Relevant information is highlighted with appropriate text layout (spacing, highlights of key points with bold, headings, and subheadings)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Informed consent forms provide clearly labeled graphs or illustrations that aid understanding (e.g., how the intervention/procedure is performed, risks)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<b>Contents</b>				
Informed consent forms describe, in the text or in the consent formula, the health condition or problem for which the intervention/exam is proposed	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Informed consent forms describe how the intervention/exam is performed	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Informed consent forms describe risks and benefits of the proposed intervention/exam	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Informed consent forms describe other available options	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Informed consent forms describe positive and negative features of the available options	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Informed consent forms describe possible harm or disadvantages in case of refusal of the proposed intervention/exam	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Informed consent forms (concerning radiological and nuclear imaging tests) describe long-term risks related to ionizing radiation	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<b>Presenting outcomes</b>				
Informed consent forms present literature rates for the outcome probabilities	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Informed consent forms allow the user to compare outcome probabilities across options using the same denominator	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<b>Evidence</b>				
Information is evidence based	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Informed consent forms provide a publication date	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Informed consent forms provide information about the update policy	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<b>Disclosure and transparency</b>				
Informed consent forms contain the denomination of the Healthcare Trust, the Healthcare Unit, and the licensing Authority	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<b>Decision support</b>				
Informed consent forms advise the patient to reflect, clarify doubts, and ask questions before deciding	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Using examples, informed consent forms help patients imagine what it is like to experience physical, psychological, and social effects	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

test is actually readable—although in practice, it has been found that real documents that are “easy to read” according to the test are likely to be easier to comprehend at a structural level. To overcome these limits, according to Montemagni et al. (22), the DyLan readability index was also

used, which can take into account factors such as structural complexity, grammatical correctness, or meaning. With this index, applicable only to Italian texts, higher values indicate harder to read text. Text layout (especially typestyle, fonts, spacing, and highlights) not assessed by readability

scores was optimized with subjective criteria inspired by the document design tips of Federal Plain Language guidelines (7).

**Field testing with patients.** We submitted either the “standard” or “revised” consent forms in a randomized sequence to 20 consecutive patients (9

**Table 2. Quantitative Assessment of Readability of Standard and Revised Informed Consent Forms**

	Italian			English		
	Standard	Revised	p Value	Standard	Revised	p Value
Flesch-Kincaid	21.09 ± 1.17	12.74 ± 0.14	<0.0001	10.23 ± 2.37	6.50 ± 0.41	<0.0015
Gulpease	45.72 ± 2.14	84.09 ± 2.98	<0.0001	41.26 ± 5.50	85.09 ± 2.61	<0.0001
Gunning Fog	25.34 ± 1.18	16.57 ± 0.33	<0.0001	13.66 ± 2.38	9.67 ± 0.73	<0.0015
Coleman-Liau	18.50 ± 0.97	15.04 ± 0.38	<0.0001	11.10 ± 1.87	8.41 ± 0.53	<0.0050
Smog	16.94 ± 1.00	8.71 ± 0.28	<0.0001	12.83 ± 1.67	9.27 ± 0.39	<0.0001
Automated readability	16.17 ± 1.30	6.44 ± 0.29	<0.0001	9.93 ± 2.68	4.84 ± 0.43	<0.0005
DyLan Lab	87.8 ± 14.12	10.34 ± 1.37	<0.0001	NA	NA	NA

NA = not applicable.

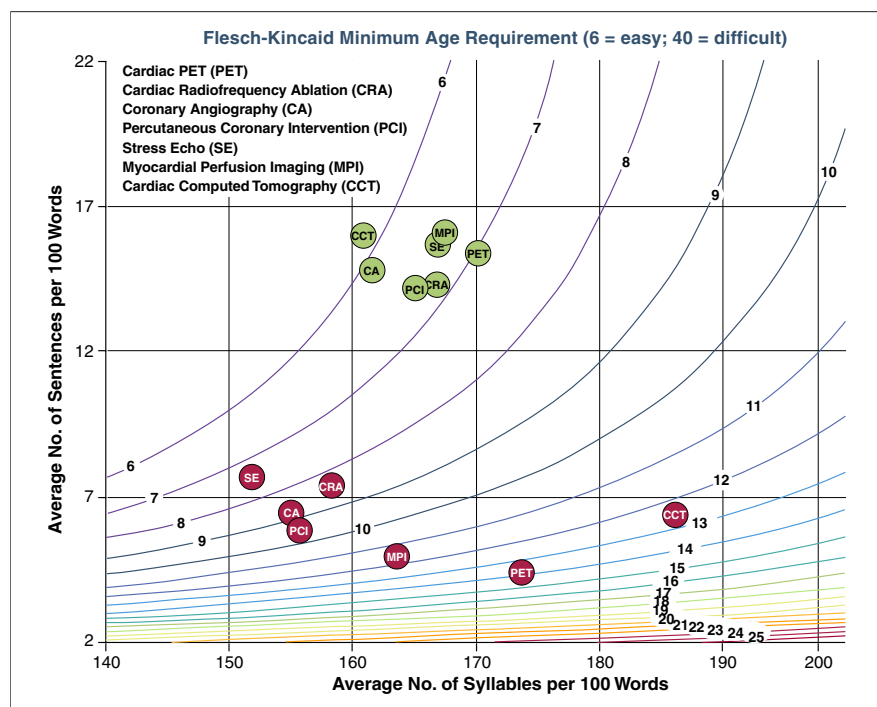
women, 11 men; ages 50 ± 18 years) admitted to the cardiac CT laboratory for a clinically driven examination. We asked them to fill in a structured questionnaire with 3 items: 1) radiation is harmless-beneficial (incorrect) or can be detrimental (correct); 2) radiation dose is zero–near zero (incorrect) or involves hundreds of chest x-rays which must be recorded (correct); 3) the imaging exam is always useful (incorrect) or is useful only when it is clinically

indicated and appropriate (correct). Answers were scored as correct (score 1) or incorrect (score 0).

**Statistical analysis.** Data were analyzed using the SPSS software package version 12 (SPSS Inc., Chicago, Illinois). Comparisons were made with the paired 2-tailed Student *t* test. The Wilcoxon Mann-Whitney test was used for comparison in the field testing. Unless otherwise indicated, data are given as mean ± SD. A value of

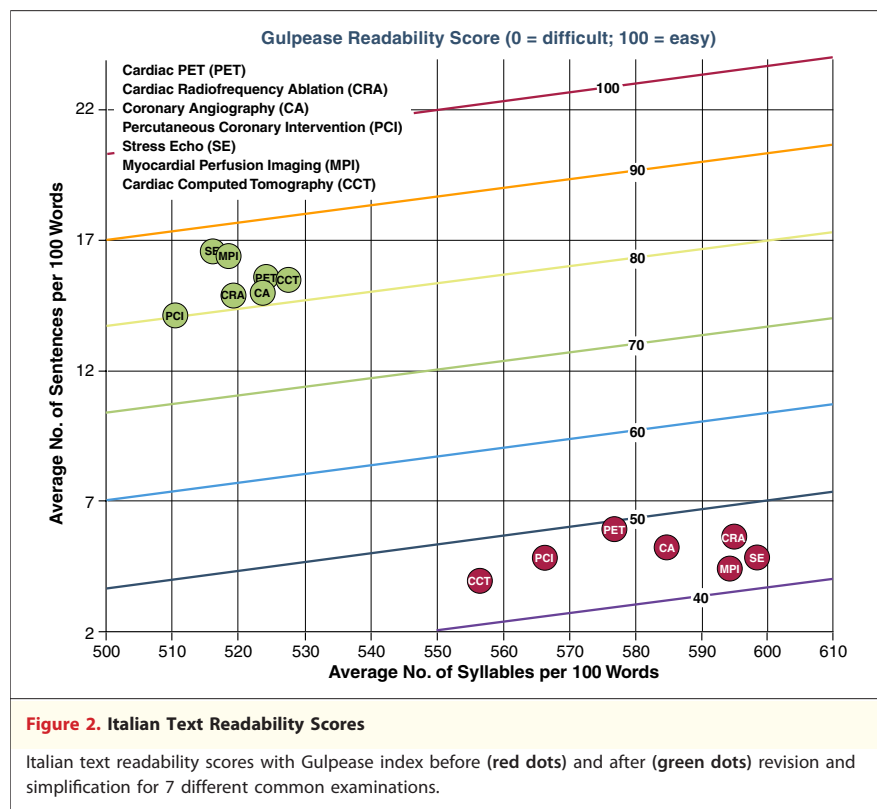
*p* < 0.05 was considered to indicate statistical significance.

**The findings.** At qualitative assessment by consensus of the expert panel, the informed consent forms were complex and poorly organized, were written in a jargon style, and contained incomplete content (not including information about treatment options, long-term radiation risk and doses); for outcome probabilities, relevant information was not properly highlighted and easy to find. An example of quality evaluation related to a specific CCT informed consent form is shown in Table 1. At quantitative analysis, readability scores were consistently low across all types of consent forms, both in the Italian and English versions (Table 2). Readability indexes were substantially improved in the revised forms, both in the English (Fig. 1) and Italian versions (Fig. 2). The revised versions also included an explicit discussion of treatment options and their relative risks and benefits, potential harm that could result from not undergoing the procedure, an explanation about long-term projected risks of ionizing radiation (which were absent or only marginally present in the original versions), and a line to be filled in after the examination that reports the actual dose (not the theoretical, expected reference dose) delivered to the patient during the examination. For the sake of ionizing radiation risk communication, a table (Table 3) and a figure (Fig. 3) were also added to the



**Figure 1. English Text Readability Scores**

English text readability scores with Flesch-Kincaid index before (red dots) and after (green dots) revision and simplification for 7 different common examinations.



revised form. The 20 patients recruited for field testing evaluated either the standard (group #1) or the revised (group #2) forms. The 2 groups were comparable for age (group #1,  $51 \pm 8$  years vs. group #2,  $50 \pm 19$  years;  $p = \text{NS}$ ), sex (5 men in group #1 vs. 6 men in group #2;  $p = \text{NS}$ ), and educational level (3 graduated participants in group #1 and 4 in group #2;  $p = \text{NS}$ ). The obtained score was  $1.2 \pm 0.6$  in group #1 and  $2.6 \pm 0.5$  in group #2 ( $p < 0.001$ ).

Communication in medicine is difficult, and a certain degree of obscurity was also functional in the old-fashioned practice of medicine fueled by paternalism and efficiency. When he was a young graduate of Harvard Medical School, Michael Crichton stated that “medical writing is a highly skilled, calculated attempt to confuse the reader” (23). Unfortunately, this is sometimes still true today, especially in the field of informed consent and risk communication. We have shown by a qualitative and quantitative (objective, operator-independent) approach that

current informed consent forms are incomplete and basically unreadable for the average patient, and they usually do not mention other treatment options and radiological risk—a projected long-term cancer risk that should be explicitly discussed and included in the risk-benefit assessment (24). Substantially higher quality levels, readability scores, and patient’s understanding of essentials of imaging can be achieved using simple revised forms based on a set of criteria regarding content, text design and layout, and development process. These revised forms should also cover and explicitly discuss radiological risk, following recommendations of the International Atomic Energy Agency 2010 document for radiological risk communication (25).

**Study limitations.** We evaluated 7 Italian and 7 English consent forms. The choice was somewhat arbitrary because there is wide deregulation in the field, in spite of explicit recommendations of scientific societies. The different techniques used for language analysis have

different strengths and limitations, as discussed in the Methods section. None can provide a complete assessment of readability in all of its complex components. However, it is reassuring that all readability scores moved coherently in the same direction and gave consistent results. We used several ways to express the effective radiation dose and risk equivalent, including the equivalence of background radiation. We used several risk estimates in ad hoc developed user-friendly software (26) with pictorial interface with a menu of risk equivalents (from cigarette smoking to highway car driving to rock climbing). This or similar software is the ideal companion of the informed consent form in a multimedia platform, which is the “next-generation” informed form. The study was completed in only 1 institution, and this can limit the generalizability of the findings. We referred to an average population risk, but the radiation risk should be personalized because it varies not only according to age and sex (taken into account in the consent form) but also with a variety of genetic, pharmacological, and environmental modifiers (such as changes in genes involved in DNA repair, antioxidant supply, and concomitant smoking habit).

**Clinical implications.** Many procedures and diagnostic exams commonly performed in cardiology imply acute, sub-acute, and long-term risks, but current consent forms do not usually provide an accurate and understandable wording of risks and usually do not mention radiation doses and long-term cancer risks at all. The consequences of this imperfect communication can impact both patients and physicians. Patients will tend to overestimate diagnostic and therapeutic benefits from imaging and interventions and underestimate the risks of these same procedures (11,12,27). Physicians are substantially more vulnerable to litigation from uninformed patients, especially in the nonrare instances of inappropriate examinations



expert of Istituto Informatica and Telematica of the Italian National Research Council; Antonio Dodaro, lawyer and expert in patients' rights; and Domenico Giofrè, biophysicist, former

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