Unreadability of current informed consent forms in cardiology - and how to improve them

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Background: Guidelines on informed consent for clinical practice and research trials recommend the use of standard plain language to enhance patient comprehension and to facilitate shared decision-making. Aim: To assess readability of our current informed consent forms used in cardiology.

Methods: We evaluated the informed consent forms, currently used in an Italian tertiary care and research center and previously set according to the recommendations of scientific societies, of 7 common examinations: 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). For each test, we also developed a revised informed consent form written by language experts assisted by cardiology specialists following federal plain language guidelines (Plainlanguage.gov, revised December 2010). We analyzed each text (standard and revised) with Flesch-Kincaid (F-K) grade level (high numbers indicating harder-to-read text) and the Italian language-tailored Gulpease level (from 0, easy, to 100, difficult).

Results: Readability was poor for the standard consent forms (red points in figure) and visibly improved with the revised form (green points) with higher readability evidenced by changes in both F-K grade level (standard: 21±1% vs revised: 12±0.4%, $p<0.001$) and Gulpease (standard=45±2 vs revised=84±2, $p<0.0001$).

Conclusion: Current informed consent forms are unreadable for the average patient. Substantially higher readability scores can be achieved with novel forms which explicitly discuss risks and are prepared following standard recommendations of plain writing.