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REVIEW

Event-based versus process-based informed consent to address scientific evidence and uncertainties in ionising medical imaging

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Abstract
Background Inappropriate ionising medical imaging has been escalating in the last decades. This trend leads to potential damage to health and has been associated to bioethical and legal issues of patient autonomy.
Methods While the doctrine underlines the importance of using informed consent to improve patient autonomy and physician-patient communication, some researchers have argued that it often falls short of this aim. There are basically two different informed consent practices. The first — the so-called "event-based model" — regards informed consent as a passive signature of a standard unreadable template, performed only once in each medical pathway. The second — the so-called "process-based model" — integrates information into the continuing dialogue between physician and patient, vital for diagnosis and treatment.
Results Current medical behaviour often embraces the event-based model, which is considered ineffective and contributes to inappropriateness. We sought, in this review, to analyse from juridical and communication standpoints whether process-based informed consent can deal with scientific uncertainties in radiological decision-making. The informed consent is still a distinctive process in defence of both patients' and physicians' health and dignity in rule-of-law states and consequently in curtailing the abuse of ionising medical radiation.

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Main Messages
- *Inappropriate ionising medical imaging is widespread and increasing worldwide.*
- *This trend leads to noteworthy damage to health and is linked to the issue of patient autonomy.*
- *Some authors have argued that informed consent often falls short of improving patient autonomy.*
- *Process-based informed consent can deal with scientific uncertainties to contrast inappropriateness.*
- *Informed consent is still a distinctive process in defence of both patients and physicians.*

Keywords Ionising radiation · Informed consent · Patient autonomy · Patient autonomy · Risk communication

Introduction

Inappropriateness of medical imaging has been a trending topic in the last few years [1–4]. The linear growth in the health care expenditures due to costs of imaging exams [5–7] along with new evidence that medical radiation may cause long-term cancer [8, 9] is contributing to the increased interest of the medical community and general population. Studies demonstrate that imaging exams are responsible for a 45 % increase in health expenditures [5]. In addition, it is estimated that up to one-third of all imaging exams are partially or totally inappropriate [3, 10]. As inappropriateness of imaging exams is seen as a potential cause of patients' harm, the current ethical and legal forms and rules are being reviewed, as well as the informed consent process, which is one of the most important tools to protect patients and physicians.

Clinical imaging has conferred undoubted benefits on modern medical practice. But this does not mitigate the fact that even with low ionising exposure every radiological or nuclear medicine examination may lead to a long-term risk

of cancer in patients [8, 9]. In the context of informed consent, individuals subjected to ionising radiation often receive inadequate or no information about the radiation exposure dose and the potential risk related to the dose received.

The main aim of this article is to discuss the role and impact of the informed consent process in patients undergoing imaging exams containing ionising radiation. The legal aspects of the informed consent process, risk communication and uncertainties within the consent process are also emphasised in this review.

The trade-off: risks and benefits of ionising imaging

Physicians must justify their decision to request an imaging exam using ionising radiation, and the decision is based on a trade-off between risks and benefits [11]. The benefits from diagnostic procedures utilising radiation must overcome the risks [12, 13]. The decision must consider the likelihood of immediate benefit as well as future damage to health [14–17]. In order to make a decision, clinicians must be familiar with the given radiation dose and the possible harmful effects of the radiation exposure [12]. Without solid knowledge of the radiation risk from imaging exams, physicians are unable to properly ponder the risks compared to potential benefits and may find it difficult to justify the exposure of patients to medical radiation [18–21]. Referral guidelines can partially replace the lack of deep knowledge [22–25]. Limited knowledge about radiation and an inadequate use of guidelines indicate a suboptimal justification of referrals [25].

Many studies reveal important shortcomings in physicians', as well as in medical students', awareness and knowledge about radiation risk [18–21]. Since today's medical students are future medical practitioners, they will be unable to make appropriate informed clinical decisions unless they are taught principles of radiation protection. A white paper of the European Society of Radiology [26]—in line with the European MED Directive [27]—emphasises that undergraduate and graduate students need to acquire a broader and deeper understanding of the hazards of radiation, patients' protection, awareness of which tests deliver a larger absorbed radiation dose, the value of alternative investigations without the use of radiation, etc. In addition, undergraduate and graduate students need to comprehend the principle of informed consent and its impact on clinical imaging and interventional procedures [28].

Informed consent

Event-based and process-based

The doctrine underlines the ideal of using informed consent to improve patient autonomy and physician-patient communication. Nevertheless, some authors argue that informed consent itself often fails to achieve this goal [29–32]. Other authors describe the difference between the doctrine and the operational application of informed consent, which is still imperfect and requires improvement [33–36].

Following a representative then simplified perspective, there are basically two manners in which to implement the informed consent (see Table 1), and they are described by two models: the event- and the process-based model. The event-based model, the one most often used [37–40], can be applied at a given moment and in any diagnostic path. This procedure must, therefore, cover all the legal elements in that precise circumstance in which the template will be subjected to being signed by the patient [36, 41]. The event-based model impedes the patient from deciding freely and deliberately, as the patient remains unaware of possible biological consequences of radiological interventions. Also, physicians are not fully protected under the event-based model, as—by using this ineffective communication approach—they can carry out unsuccessful clinical acts more frequently, with legal consequences. Research has shown that effective patient-physician communication can improve health outcomes [42–45]. On the other hand, a lack of physician-patient communication also generates more recurrent medical litigations [46–49]. The event-based model is considered ineffective [37, 41, 50, 51], additionally contributing to inappropriateness, as only written information is provided and this does not necessarily imply that patients are truly informed about the risks and benefits of the examination and potential alternatives [52, 53].

The process-based model, on the contrary, integrates the information process to the patients in an outgoing dialogue with the physicians as part of the diagnostic and treatment routine [36, 41]. Authors suggest that the process-based model shows many advantages compared to the event-based model, such as enhancing the physician-patient interaction, thus the responsibility from both parts [36, 41].

General approach

The arbitrary nature of the medical act is well known in Italian criminal law, which prosecutes illegal medical acts such as the lack of informed consent, providing inadequate or incomplete information, and communicative disclosure between the physician and patient.

After being fully informed by their physicians, patients should carefully read the consent form before agreeing with the medical act [54–57]. If patients are unaware of the radiation risk from imaging exams, they will therefore not perceive the intrinsic danger; consequently, a signature on the consent form will not be legally valid.

Physicians have an ethical and legal responsibility when requesting a patient to sign a consent form agreeing to a risky

Table 1 Two models of informed consent implementation [36, 41]

Dimensions	Event-based model	Process-based model
Time span	The decision must be regarded as an act placed in a limited and short time span, in which the physician provides the patient with all the information about the diagnosis procedure that he/she intends to adopt. The patient will have to accept it or reject it	The decision is determined and defined continuously throughout the time span of the diagnostic process and therefore of the doctor-patient relationship. The consensus is built on the perspective of an active participation by the patient with the medical decision-making
Procedure	Informed consent is an additional procedure within the unchanged decision-making process	Informed consent is integrated into the doctor-patient relationship as a transverse component to all the aspects of information/communication and the clinical decision-making processes
Involved actors	The consent can be gathered from any health operator belonging to the involved staff	The consent is collected by the physician who proposes the diagnostic act
Central focus	The consent form is considered as the backbone of the event model. The importance of providing complete and accurate information that meets most of the legal requirements of the informed consent process is emphasised	The focus of the "process" model is not so much the module itself, but rather a series of information and communicative acts that—together with the module itself—are performed within the diagnostic process
Interaction	A more bureaucratic interaction is produced, with two consequences: the perception by physicians of a sense of futility; the perception by patients that their real participation in decision-making is neither sought nor important	The model requires that the doctor and patient enter into an ongoing dialogue, which is defined as "mutual monitoring"
Perspective	The consent is given as part of the medical act limited to the diagnosis date	Informed consent is an integral part of the therapeutic alliance, as a vision that is generated in the doctor-patient relationship and extends in a broad sense to the structure, the territory and the National Health System

medical act [58–60]. The possibility of a patient developing cancer as a result of ionising radiation is often omitted by the physician requesting or performing the imaging exam. This is the result of several malfunctions such as poor interaction and/or communication between the physician and patient, lack of clinical appropriateness and lack of organisational appropriateness. The latter is a cause of internal diseconomies within clinical structures, where ionising imaging represents a large segment of clinical practice. Specifically, these diseconomies include (1) an increased incidence of civil litigation; (2) increased insurance premiums for medical responsibility; (3) a consequent refusal by insurance companies to assume the warranty of the clinical risks; (4) longer waiting lists; (5) more general and unsustainable waste in healthcare expenditures.

The physicians must justify their own prescriptions, from a clinical and legal standpoint, as well as the carrying out the procedure. The Euratom Law states that an examination involving radiation exposure must be justified in advance before a patient is referred to a radiologist or nuclear medicine physician [27]. The justification integrates scientific and clinical elements with a certain type of ionising technology to be used. Therefore, it is precisely in this correlation between the use of ionisation and the specific patient's disease that the legal right to "real" informed consent is acknowledged [58–60]. According to some authors, it is reasonable that the provision of risk information within the informed consent process should be mandatory only for procedures with a radiation dose higher than 1 mSv, such as CT, nuclear medicine exams, positron emission tomography (PET), PET/CT and fluoroscopic procedures [58, 61, 62].

An important problem linked to informed consent is the time factor, whether informed consent expressed immediately before the execution of the radiological procedure is legally valid [59, 60]. In response to this question concerning the timing of informed consent, we should remember that information, dialogue and trust between the physician and patient should exist within a planned and active clinical implementation [61]. Thus, it is imperative an appropriate chronological separation between conveying the information to the patient and the implementation of the procedure utilising radiation [60]. Only in this way, can the communicative and legal intent be preserved in order to minimise any psychological coercion connected to the time factor influencing the willingness of the patient to provide informed consent. The decision-making autonomy of the patient—*a fortiori* and in this specific type of informed consent—cannot be constrained by the time factor, which even more strongly collides with the specific scientific and clinical significance of the radiological risk, as well as with complex problems related to effective communication [58–60].

Results from a study showed that communication, time to talk and information are probably the most important features that patients desire from their physicians, including from radiologists [63]. A study [64] demonstrated, that even in a busy practice driven by time constraints and financial pressure, 80 % of the patients were satisfied and were able to convey their problems to physicians in only 2 min of interaction [64].

Therefore, physicians should not blame their busy schedule to justify poor interaction with their patients or a lack of time to properly explain the risks and benefits of complementary exams to their patients.

Risk communication

Risk communication is a projection of the legal duty of the physician. This projection should be related to the patients' rights to have input concerning medical acts that could damage their health or expose them to a real middle- or long-term danger of death. Failure to provide such information to the patient in the context of informed consent can subsequently (and in court) lead to the investigation and possible conviction of the professional who performed an arbitrary act of ionising imaging. This occurs when the physician—prior to the exam—does not explain the risks and benefits connected to the diagnostic act to the patient, and the patient cannot exercise an explicit, free and conscious choice (acceptance or rejection).

Another aspect of informed consent in ionising medical imaging regards the concept of population statistics and risks [29]. Many studies about risk communication have addressed the difficulty of conveying correct information to patients, and they have suggested interesting solutions [65–68], such as the use of visual displays [66, 68]. Visual displays include risk ladders, human and Chernoff faces, line graphs, dots and Xs in which the Xs represent those affected by the hazard, marbles, pie charts and histograms. Evidence mostly suggests that combining visuals with numerical and written descriptions improves the perceived helpfulness of the information and the accuracy of perceived risk [68]. Another solution is provided by consistent and robust literature showing that people better understand risk information (in terms of gross comparison and risk assessment tasks) if risks are presented in terms of frequencies (e.g., 5 out of 100 people) rather than in percentages (5 %) [66, 69].

Scientific uncertainty as an obstacle in informed consent

The role of the physician is arguable in certain situations, such as when the physicians have to share scientifically controversial data with their patients, even if the data are significant, such as the potential cancer risk of low levels of medical radiation [29]. These uncertainties are expressed in terms of scientific reliability from a clinical and legal standpoint, generating many consequences. We refer in particular to managing these uncertainties in the context of risk communication, as an atypical legal duty inherent in informed consent in radiology and nuclear medicine. Uncertainties in risk can jeopardise the fundamental right to patients' health and should not be omitted by the physicians. Uncertainties can be determined and clarified via risk communication solutions and by providing a justification and consideration of risks and benefits, essential elements in obtaining informed consent for any medical act that may have potential risk [70].

Some authors argue that informed consent cannot account for stochastic risk uncertainties [29]. In this scenario, patients must be fully informed of what is known and what is unknown, but it is not advisable to establish a contract between a patient and the physician that reflects uncertainty [29]. On the contrary, we claim that patients must be fully informed about the potential risks in order to provide their consent, even if the potential risks are based on controversial scientific data.

The main dispute relating to discussing radiation risk with patients focusses on the certitude of radiation risk estimates [61] and the linear no-threshold risk model for assessing potential correlation between radiation and cancer. It is necessary to take into account several important factors, as proposed in the following points.

(1) The linear no-threshold risk model is endorsed by all the major radiation regulatory boards, including the International Commission on Radiological Protection [11, 12], the National Academy of Sciences BEIR committee [71], the United Nations Scientific Committee on the Effects of Atomic Radiation [72] and the US Food and Drug Administration [73]. The BEIR VII summary claims that, at lower doses without a threshold, the cancer risk progresses in a linear fashion and that even the smallest dose can potentially provoke a slight increase in cancer risk to humans [71]. Low dose is defined by the BEIR VII committee as doses ranging from zero to 100 mSv.
(2) Most published articles that examine medical radiation in a scientific fashion suggest a significant risk [9, 74–76].

The tendency to justify a mild misperception of low risk has no scientific basis and is misleading from a legal standpoint. This is significant for radiologists or any physician who requests an imaging exam. We cannot ignore the scientifically proven fact that the different types of ionising radiation, artificial or natural, produce a cumulative effect of low-level chronic exposure and are related to adverse effects on human cells [4, 13, 22, 23].

Efforts can be made to assess the relative importance of the several epidemiological uncertainties. There are some approaches to quantifying uncertainties in lifetime attributable risk, like for instance that followed by the Monte Carlo method [77]. Nevertheless, the linear no-threshold model is still considered as the most robust model for medical decision-making about radiation exposure and cancer risk.

This model should be used in conjunction with general dose optimisation strategies [27] and increased use of protocols [27] and patient-individualised information [77].

The attention to scientific uncertainty opens a reflection of alternative and non-ionising diagnostic procedures, justified by similarities of diagnostic information and management of clinical cases. Accordingly, the Euratom Law establishes that a non-ionising technique must be used whenever it will provide information grossly comparable to that provided by an ionising radiation technique [27].

From this viewpoint, the problem focussed on should not be "whether" informed consent should be performed or not, but rather "how" this universal legal institution should deal with the ever-present scientific uncertainties [70]. The real problem is how to communicate risk in a way that is understandable to the patient. Informed consent should include risk uncertainties [70]. If this were not so, not only all informed consent forms (even those for issues other than ionising imaging), but also all drug leaflets (in which there is a contract subtended between a consumer and a pharmaceutical company) would be eliminated. In fact, all the risks that are normally described within informed consent deal with uncertainties and intrinsically have a stochastic nature.

Conclusion

Information and clinical argumentation within the framework of informed consent in radiology and nuclear medicine have significant legal importance. One aspect is the degree of validity of scientific sources on which effective risk communication about ionising radiation should be based. There should be particular focus on evidence-based medicine, which should be state of the art in every branch of medical research. Thus, the legal principles of diligence, prudence and expertise, which every physician must follow when carrying out a medical act, should be extended to the preventive obligation of clinical information and communication in the context of informed consent.

The legal validity of informed consent for ionising imaging cannot allow omission of information dictated by scientific and clinical uncertainties. On the contrary, if well-communicated by the physician, uncertainty can proactively contribute to the formation of a conscious decision by the patient.

In the eyes of the law, two key aspects must be considered.

(1) The evaluation of the continuous training of radiologists and nuclear medicine physicians in relation to the technical-scientific sources to be used in the context of the overall informed consent process. These sources should be characterised by scientific rigor and the presence of scientific data—with consequent clinical information—that are worthy of note. Currently, this can be provided accurately by means of evidence-based medicine.

(2) The continuous training of radiologists and nuclear medicine physicians in the techniques and tools of physician-patient communication and risk communication. Physician must be able to discuss technical knowledge with the patient and to deal with patient's feeling of "fear" whenever patients are subjected to risky clinical activities such as ionising imaging. Information and communication by the physician should be calibrated according to the specific pathological condition of the patient. This justifies both the correctness of the act of ionising imaging and the validity of the resulting consensus expressed by the patient.

This perspective, founded on a process-based vision of informed consent and shared decision-making, deserves to be extended under both a clinical and legal profile, even to informed consent characterised by a "contract" matrix, typically conceived and applied within the framework of the Anglo-Saxon legal tradition.

On this basis, the subject of informed consent in ionising medical imaging, although addressed differently in legal profiles in the different worlds of Common Law and Civil Law, appears analogous if we focus on the information and communication process regarding radiation risk when implementing informed consent. It is a unique methodological approach, applicable with respect to both the law as applied in the Western world and going beyond state borders. This reinforces the idea that the concrete implementation of the informed consent process in ionising medical imaging is the only way to:

- Protect the universal patient right to decide on their psycho-physical well-being in the context of "risky" acts of nuclear and radiological medicine.
- Allow physicians to develop greater communication skills and be legally protected, within a framework currently characterised by major doubts, issues and aspects of inappropriateness, both operational and relational.

Certainty regarding this topic must be ascribed to ethical and legal condemnation, in both Common Law and Civil Law jurisdictions, of all those attitudes and behaviours of defensive medicine or characterised by the lack of appropriate communication, at the levels of both the structures and the individual doctor-patient relationship.

Following our analysis of the main problems linked to the controversy about scientific uncertainties, we concur with a series of authors that informed consent is still a distinctive process that defends patient health as well as both patient and physician dignity and autonomy in rule-of-law states [18, 61, 70, 78, 79]. By means of an overall strategy and model of

communication, shared decision-making and balanced legal protection, one will be able to implement the best possible informed consent, founded on a "process-based" vision. This can contribute significantly to patient autonomy, radiation protection and appropriateness in ionising medical imaging.

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Conflict of interest The authors declare no conflicts of interest.

References

1. National Council on Radiation Protection and Measurements (2009) Ionizing radiation exposure of the population of the United States. Report No. 160. Bethesda (MD): NCRP; Mar 3
2. International Marketing Ventures, Medical Information Division (2008) Benchmark reports on CT, 2006–2008. Des Plaines (IL): IMV
3. Hall EJ, Brenner DJ (2008) Cancer risks from diagnostic radiology. Br J Radiol 81(965):362–378
4. Amis ES Jr, Butler PF, Applegate KE, Birnbaum SB, Brateman LF, Hevezi JM et al (2007) American College of Radiology white paper on radiation dose in medicine. J Am Coll Radiol 4:272–284
5. Hendel RC (2008) Utilization management of cardiovascular imaging pre-certification and appropriateness. JACC Cardiovasc Imaging 1(2):241–248
6. Lee SI, Saokar A, Dreyer KJ, Weilburg JB, Thrall JH, Hahn PF (2007) Does radiologist recommendation for follow-up with the same imaging modality contribute substantially to high-cost imaging volume? Radiology 242(3):857–864
7. Iglehart JK (2006) The new era of medical imaging—progress and pitfalls. N Engl J Med 354(26):2822–2828
8. President's Cancer Panel (2010) 2008-2009 Annual Report. Reducing Environmental Cancer Risk, What We Can Do Now. Available online: http://deainfo.nci.nih.gov/advisory/pcp/annualReports/pcp08-09rpt/PCP_Report_08-09_508.pdf (accessed December 5, 2012)
9. Berrington de González A, Darby S (2004) Risk of cancer from diagnostic X-rays: estimates for the UK and 14 other countries. Lancet 363(9406):345–351
10. Picano E, Pasanisi E, Brown J, Marwick TH (2007) A gatekeeper for the gatekeeper: inappropriate referrals to stress echocardiography. Am Heart J 154:285–290
11. ICRP (2007a) The 2007 Recommendations of the International Commission on Radiological Protection. ICRP Publication 103. Ann ICRP 37(2–4)
12. ICRP (2007b) Radiation protection in medicine. ICRP Publication 105. Ann ICRP 37(6):1–64
13. Picano E (2004a) Sustainability of medical imaging. BMJ 328(7439):578–580
14. Tversky A, Kahneman D (1981) The framing of decisions and the psychology of choice. Science 211(4481):453–458
15. Ainslie G (1975) Specious reward: a behavioral theory of impulsiveness and impulse control. Psychol Bull 82(4):463–496
16. Ainslie GW (1974) Impulse control in pigeons. J Exp Anal Behav 21(3):485–489
17. Chung SH, Herrnstein RJ (1967) Choice and delay of reinforcement. J Exp Anal Behav 10:67–74
18. Picano E (2004b) Informed consent and communication of risk from radiological and nuclear medicine examinations: how to escape from a communication inferno. BMJ 329(7470):849–51
19. Wong CS, Huang B, Sin HK, Wong WL, Yiu KL, Chu Yiu Ching TA (2012) A questionnaire study assessing local physicians, radiologists and interns' knowledge and practice pertaining to radiation exposure related to radiological imaging. Eur J Radiol 81(3):e264–e268
20. Carpeggiani C, Kraft G, Caramella D, Semelka R, Picano E (2012) Radioprotection (un)awareness in cardiologists, and how to improve it. Int J Cardiovasc Imaging 28(6):1369–1374
21. Lee CI, Haims AH, Monico EP, Brink JA, Forman HP (2004) Diagnostic CT scans: assessment of patient, physician, and radiologist awareness of radiation dose and possible risks. Radiology 231:393–398
22. Royal College of Radiologists (2007) Making the best use of clinical radiology services, 6th edn. London
23. EC European Commission (2008) Radiation protection 118: referral guidelines for imaging. Available online: http://ec.europa.eu/energy/nuclear/radioprotection/publication/doc/118_update_en.pdf - Update Mars 2008 (accessed December 5, 2012)
24. American College of Radiology (2009) ACR Appropriateness Criteria. Available via http://gm.acr.org/SecondaryMainMenuCategories/quality_safety/app_criteria/pdf/ExpertPanelonPediatricImaging/SeizuresChildDoc7.aspx. Accessed 10 November 2012
25. Borgen L, Stranden E, Espeland A (2010) Clinicians' justification of imaging: do radiation issues play a role? Insights Imaging 1(3):193–200
26. European Society of Radiology (ESR) (2011) Undergraduate education in radiology. A white paper by the European Society of Radiology. Insights Imaging 2(4):363–374
27. Euratom (1997) Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/466/EURATOM. Official J. L-180 of 09 July
28. European Commission (1998) Guidance for protection of unborn children and infants irradiated due to parental medical exposures, radiation protection 100, EC, Luxembourg
29. Brink JA, Goske MJ, Patti JA (2012) Informed decision making trumps informed consent for medical imaging with ionizing radiation. Radiology 262(1):11–14
30. Woods S, Hagger LE, McCormack P (2012) Therapeutic Misconception: Hope, Trust and Misconception in Paediatric Research. Health Care Anal 2012 Feb 18
31. Manson NC, O'Neill O (2007) Rethinking informed consent in bioethics. Cambridge University Press, Cambridge
32. Pape T (1997) Legal and ethical considerations of informed consent. AORN J 65(6):1122–1127
33. Rathor MY, Rani MF, Shah AM, Akter SF (2011) Informed consent: a socio-legal study. Med J Malaysia 66(5):423–428
34. Lidz CW (2011) Informed consent: a critical part of modern medical research. Am J Med Sci 342(4):273–275
35. Marks P (2003) The evolution of the doctrine of consent. Clin Med 3(1):45–47
36. Lidz CW, Appelbaum PS, Meisel A (1988) Two models of implementing informed consent. Arch Intern Med 148:1385–1389
37. Kirby R, Challacombe B, Hughes S, Chowdhury S, Dasgupta P (2013) Increasing importance of truly informed consent: the role of written patient information. BJU Int. Feb 18
38. Leclercq WK, Keulers BJ, Scheltinga MR, Spauwen PH, van der Wilt GJ (2010) A review of surgical informed consent: past, present, and future. A quest to help patients make better decisions. World J Surg 34(7):1406–1415
39. Jefford M, Moore R (2008) Improvement of informed consent and the quality of consent documents. Lancet Oncol 9(5):485–493

40. Arnold SV, Decker C, Ahmad H, Olabiyi O, Mundluru S, Reid KJ, Soto GE, Gansert S, Spertus JA (2008) Converting the informed consent from a perfunctory process to an evidence-based foundation for patient decision making. Circ Cardiovasc Qual Outcomes 1(1):21–28
41. Dodaro A, Recchia V (2011) Inappropriateness in ionizing imaging. The central node of the informed consent: from "event" model to "process" model. Recenti Prog Med 102(11):421–431
42. Bull SA, Hu XH, Hunkeler EM, Lee JY, Ming EE, Markson LE et al (2002) Discontinuation of use and switching of antidepressants: influence of patient-physician communication. JAMA 288(11):1403–1409
43. Ciechanowski PS, Katon WJ, Russo JE, Walker EA (2001) The patient-provider relationship: attachment theory and adherence to treatment in diabetes. Am J Psychiatry 158(1):29–35
44. Bogardus ST Jr, Holmboe E, Jekel JF (1999) Perils, pitfalls, and possibilities in talking about medical risk. JAMA 281(11):1037–1041
45. Stewart MA (1995) Effective physician-patient communication and health outcomes: a review. CMAJ 15(9):1423–1433
46. Moore P, Vargas A, Núñez S, Macchiavello S (2011) A study of hospital complaints and the role of the doctor-patient communication. Rev Med Chil 139(7):880–885
47. Gallagher TH, Waterman AD, Ebers AG, Fraser VJ, Levinson W (2003) Patients' and physicians' attitudes regarding the disclosure of medical errors. JAMA 289(8):1001–1007
48. Levinson W, Roter DL, Mullooly JP, Dull VT, Frankel RM (1997) Physician-patient communication. The relationship with malpractice claims among primary care physicians and surgeons. JAMA 277(7):553–559
49. Hickson GB, Clayton EW, Entman SS, Miller CS, Githens PB, Whetten-Goldstein K, Sloan FA (1994) Obstetricians' prior malpractice experience and patients' satisfaction with care. JAMA 272(20):1583–1587
50. Wilhite CL (2010) Informed consent: it is more than just a document. Plast Surg Nurs 30(4):259–261
51. Department of Health (2001) 12 key points on consent: the law in England. The Stationery Office, London
52. Killewich LA, Falls G, Mastracci TM, Brown KR (2011) Factors affecting radiation injury. J Vasc Surg 53(1 Suppl):9S–14S
53. Dodaro A (2011) Clinical appropriateness and informed consent in the Italian hospitals. Juridical problems and safeguard of patient's and physician's rights. Recenti Prog Med 102(7-8):296–301
54. Helitzer DL, Lanoue M, Wilson B, de Hernandez BU, Warner T, Roter D (2011) A randomized controlled trial of communication training with primary care providers to improve patient-centeredness and health risk communication. Patient Educ Couns 82(1):21–29
55. Zuckerman M (2006) Sensation seeking and risky behavior. American Psychological Association, New York
56. Leigh BC (1999) Peril, chance, adventure: concepts of risk, alcohol use and risky behavior in young adults. Addiction 94(3):371–383
57. Rotter J (1990) Internal versus external control of reinforcement: a case history of a variable. Am Psychol 45(4):489–493
58. Malone J, Guleria R, Craven C, Horton P, Järvinen H, Mayo J, O'reilly G, Picano E, Remedios D, Le Heron J, Rehani M, Holmberg O, Czarwinski R (2012) Justification of diagnostic medical exposures: some practical issues. Report of an International Atomic Energy Agency Consultation. Br J Radiol 85(1013):523–538
59. IAEA International Atomic Energy Agency (2009a) Justification of medical exposure in diagnostic imaging: Proceedings of an International Workshop Held in Brussels, Belgium, 2-4 September
60. IAEA International Atomic Energy Agency (2009) Report of a consultation on justification of patient exposures in medical imaging. Radiat Prot Dosim 135(2):137–144
61. Semelka RC, Armao DM, Elias J Jr, Picano E (2012) The information imperative: is it time for an informed consent process explaining the risks of medical radiation? Radiology 262(1):15–18
62. Andrieu N, Easton DF, Chang-Claude J, Rookus MA, Brohet R, Cardis E, Antoniou AC, Wagner T, Simard J, Evans G, Peock S, Fricker JP, Nogues C, Van't Veer L, Van Leeuwen FE, Goldgar DE (2006) Effect of chest X-rays on the risk of breast cancer among BRCA1/2 mutation carriers in the international BRCA1/2 carrier cohort study: a report from the EMBRACE, GENEPSO, GEO-HEBON, and IBCCS Collaborators' Group. J Clin Oncol 24(21):3361–3366
63. Capaccio E, Podestà A, Morcaldi D, Sormani MP, Derchi LE (2010) How often do patients ask for the results of their radiological studies? Insights Imaging 1(2):83–85
64. Langewitz W, Denz M, Keller A, Kiss A, Rüttimann S, Wössmer B (2002) Spontaneous talking time at start of consultation in outpatient clinic: cohort study. BMJ 325(7366):682–683
65. Klein WM, Stefanek ME (2007) Cancer risk elicitation and communication: lessons from the psychology of risk perception. CA Cancer J Clin 57(3):147–167
66. Fagerlin A, Ubel PA, Smith DM, Zikmund-Fisher BJ (2007) Making numbers matter: present and future research in risk communication. Am J Health Behav 31(Suppl 1):S47–S56
67. Edwards A, Elwyn G (2001) Understanding risk and lessons for clinical risk communication about treatment preferences. Qual Health Care 10(Suppl 1):i9–i13
68. Lipkus IM, Hollands JG (1999) The visual communication of risk. J Natl Cancer Inst Monogr 25:149–163
69. Hoffrage U, Gigerenzer G (1998) Using natural frequencies to improve diagnostic inferences. Acad Med 73(5):538–540
70. Hoffman FO, Kocher DC, Apostoaei AI (2011) Beyond dose assessment: using risk with full disclosure of uncertainty in public and scientific communication. Health Phys 101(5):591–600
71. National Research Council (2005) Executive summary. In: Health risks from exposure to low levels of ionizing radiation: BEIR VII. National Academies Press, Washington, DC
72. UNSCEAR (2000) Report to the general assembly. In: United Nations Scientific Committee on the effects of atomic radiation. United Nations, New York, NY
73. FDA U.S. Food and Drug Administration (2005) What are the radiation risks from CT? http://www.fda.gov/cdrh/ct/risks. Accessed July 15, 2012
74. Eisenberg MJ, Afilalo J, Lawler PR, Abrahamowicz M, Richard H, Pilote L (2011) Cancer risk related to low-dose ionizing radiation from cardiac imaging in patients after acute myocardial infarction. CMAJ 183(4):430–436
75. Einstein AJ, Weiner SD, Bernheim A, Kulon M, Bokhari S, Johnson LL, Moses JW, Balter S (2010) Multiple testing, cumulative radiation dose, and clinical indications in patients undergoing myocardial perfusion imaging. JAMA 304(19):2137–2144
76. Smith-Bindman R, Lipson J, Marcus R, Kim KP, Mahesh M, Gould R, Berrington de González A, Miglioretti DL (2009) Radiation dose associated with common computed tomography examinations and the associated lifetime attributable risk of cancer. Arch Intern Med 169(22):2078–2086
77. Shah DJ, Sachs RK, Wilson DJ (2012) Radiation-induced cancer: a modern view. Br J Radiol 85(1020):e1166–e1173
78. Terranova G, Ferro M, Carpeggiani C, Recchia V, Semelka R, Picano E (2012) Unreadability of current informed consent forms in cardiology—and how to improve them. JACC Cardiovasc Imaging 5(6):649–655
79. FRO Faculty of Radiation Oncology (2010) Guidelines for informed consent, version 2. The Royal Australian and New Zealand College of Radiologists. Available from URL: http://www.ranzcr.edu.au