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From Actors to Authors

A First Account About the Involvement of Patients in the Informed Consent Governance of a Major Italian Translational Research Hospital

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Abstract: From 2007 to 2009 *Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico*, one of the major public research hospitals in Italy, has invested on a participatory action to promote a good practice of informed consent. The project focused on the improvement and innovation of informed consent considered as a participated act through the involvement of all the actors at stake. The main purpose was to improve the informative practices through the participatory innovation of institutional and organizational elements as conditions of possibility. Therefore the project has pursued the involvement of managers, healthcare professionals, patients and their associations in the institutional governance of informed consent. The involvement of citizens and patients within the whole process meant to put them in charge not just as actors or final evaluators of a good practice, but as co-authors in defining standards, tools and conditions for a good practice. Several actions were taken, including a phase of analysis which involved 20 patients from 8 Associations, a phase of innovation and education where 113 patients and citizens worked together with clinicians from 53 Units in deliberative laboratories, the institution of a multidisciplinary committee inclusive of representatives from 6 associations of patients.

The project has produced different outcomes: new institutional guidelines adopted by the hospital; the renewal of consent forms and procedures as part of an explicit shared informative process; an increased implementation of institutional standards of good informative practice; the measure and communication of the outcomes of care and their bench-marking; bottom-up building of paths of validation; the creation of participatory electronic tools; an innovative education on the field for patients and clinicians. **Key words:** *deliberative approach*, *informed consent*, *participation*, *patients' involvement*, *shared decision-making*

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INFORMED CONSENT has become a common practice in contemporary medicine and it is usually taken for granted in different contexts and sanitary acts for very diverse patients. However, the perception is that it does not always correspond to good practice. The diverse practices of information, decision making, and consents to ordinary treatments in everyday clinical activity are in fact implemented more as a legal, formal duty rather than as a real good practice where patients are recognized as interlocutors in sharing knowledge and decision processes, which implies a deep cultural change for managers and clinicians.

From 2007 to 2009, with a purpose of looking for an innovative informed consent governance, Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, one of the major public research hospitals in Italy, has invested on a wide participatory action to promote a good practice of informed consent, "Il consenso in corsia," a project involving all the actors at stake. The issue of informed consent had been to that point intended as a formalistic and organizational topic. The project was quite a new undertaking within the hospital because it has been meant both as a deliberative research action in clinical bioethics and as a local process of participated clinical governance and good practice implementation. This double-sided configuration has been considered ideal to experiment on the field on how the participatory approach could change the way informative practices were innovated and evaluated while already producing changes and improvements within the everyday practice of more than 50 clinical units, ranging from pediatrics to gynecology, general surgeries to organ transplantation, internal medicines to specialized diagnostics, and cellular therapy to biobanking.

A key aspect of our research has been involvement intended as a participatory method and as a concrete experience of recognition and collaboration. The project was in fact a chance to involve a large and varied audience of patients who, as everyday actors of a multifaceted practice, could become actual agents in improving the quality of the practice itself. Hence, together with clinicians and managers, they have been involved into being good practice designers and mutual educators.

The large scope of the project, the plurality of actors, and the uncertainty of clinical knowledge have suggested to face informed consent in terms of complexity (Funtowicz & Ravetz, 1993). This complexity, which we have assumed from the beginning but whose characteristics also emerge from the field and the interlocutors, lies on a double level, the first one is the clinical relationship itself as shared space of knowledge, care, and decision making, the second one is its institutional governance.

At the level of clinical practice, complexity included the uncertainty of knowledge (Pellizzoni, 2005) about risks, outcomes, and prognosis; and the plurality of values, experiences, and logics of the actors at stake, which is amplified by the significant number of diversely vulnerable subjects involved (children, seniors, foreigners, and chronic/expert patients).

At the level of governance, complexity included economic and organizational constraints; diverse mindsets and priorities between managers, clinicians, and patients; and multiple relationships of the informed consent issues with different fields such as quality improvement, risk management, and insurance coverage.

Given these premises, the project has focused on informed consent considered as a good practice and a participated act whose

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effective governance can be pursued through the active involvement of all its own actors. This focus on the involvement as a feature of both the practice and its governance has been seen as the essential methodological counterpart to the above-mentioned double-layered complexity (Casati, 2003; Gracia, 2004). In this sense, although informed consent as a process is a faced issue in clinical bioethics, it is still quite an open field when it comes to actually provide implementation to participatory practices where patients, professionals, and institutional subjects cooperate together and are coauthors of the whole process that leads to a good clinical informative practice.

RATIONALE OF THE PROJECT

One of our main assumptions was the necessity to improve a good informative practice through the innovation of the institutional and organizational elements that are conditions of its possibility. The project, thus, has pursued the involvement of institutional representatives and managers all along with health care professionals, patients, and their associations. In this way, knowledge coproduction and shared decision making have been not just ends to be implemented for a good practice of informed consent but also means of the processes of analysis and innovation (Jasanoff, 2004). Patients and citizens, in particular, were in charge not just as actors or final and formal evaluators of a good practice but also as coauthors of the whole process that leads to define standards, tools, and conditions for a good practice from initial planning to institutional policies.

Consequently, the participatory approach has not been exclusively conceived as an act of involvement of patients, but, more widely, a process of mutual recognition between all actors at stake. In fact, if we assume that informed consent is a good practice only when all the points of view are considered and the uncertainty of knowledge is taken into account, we need to warrant adequate conditions of pluralism and knowledge coproduction. To meet such requirements, we stressed the relevance of balanced and comprehensive inclusion of all the 3 actors, not just the historically most discriminated patient as recipient of services.

At the level of governance, institution, professionals, and patients interplay to evaluate practices and innovate the organization by sharing priorities and problems: patients and professionals give their expertise and the institution guarantees the conditions of possibility, in terms of means to monitor the quality and of organizational time and space to implement it. More in detail, shared decision making requires correct information on the medical act at stake, in other words it needs tailored and contextualized information. Although tailored information arises from a knowledge exchange between professionals and patients, contextualized information implies the monitoring of medical acts performances and related risks. The more professionals know and monitor about their practices, the better they will inform and the institution will guarantee the patient's security.

This participatory approach implements a space of debate with a specific logic training—the requirements and standards of good practice are not already given but reengineered so that their implementation is understood and taken responsibly. The critical questions and the consequent training needs have emerged on the field, through discussion of practices in use during workshops scheduled among the actors involved. These comparisons among the different recipients of information—the patient, the practitioner, and the institution—have been in itself highly formative and led to a concrete bottom-up building of

- in-training instruments;
- innovative paths of validation; and
- an interactive Web site (http://www.formazione.eu.com/consenso/Default.aspx?st=008000000000000) and a virtual office, a Web platform (http://direzionescientifica.updatelog.com/) to share the activities in a perspective of transparency and coproduction in order to update the informative practices.

Most activities of the project have been institutionally considered as continuing medical

education for the health care professionals, thus recognizing the coordinated and innovative action on the field as an essential part of their learning commitments.

In terms of evaluation, the project due to be focused on good informative practice taken as process and in its collegiality faced the aspect of verification in a consistent way, identifying not only a set of indicators but also an innovative assessment practice.

STEP-BY-STEP PROJECT

A concrete starting point: The participatory monitoring of the state of art

The project was aimed first to the analysis of the existent practices and the preliminary empowerment of all the actors including the use of the following.

The review of all consent forms

1. All 56 units were requested to submit their 753 consent forms for a comprehensive review through a series of criteria about identification elements and informative contents that were elaborated from international standards and shared with the units before the review process. The review was undertaken independently by eight people—experts, researchers, and managers—and showed how some identification elements were largely absent within the majority of consent forms (Table 1). Some informative contents were widely lacking as well (Table 2).
2. Twenty representatives from eight associations* of patients discussed logic, style, and language of eight consent forms in use to elaborate a *Vademecum* for good informative practice that later became a basis for the elaboration of the new institutional guidelines. At the same time they tested a Web platform Consensus Engine (http://www.consensusengine.eu/corsia/) to create virtual tables of discussion from a distance.

Table 1. Analysis on 753 Consent Forms at the Beginning of the Project: Identification Elements

Identification Element	No (%)	Yes (%)
Patient name	6.1	93.9
Patient birth date	20.8	79.2
Date of consent	6.5	93.5
Procedure ID	18.5	81.5
Physician ID	32.3	67.7
Physician signature	55.4	44.6
Readable fonts	8.1	91.9
Patient information signature	84.7	15.3
Patient consent signature	2.9	97.1

A series of preliminary encounters with clinicians

A group of professionals from each unit met to discuss the results of the review process, verify the opportunity of an electronic matrix to guide the elaboration of forms, and gather their feedback about the state of the informative practices within their everyday activity, for a total of 56 meetings. Every meeting was institutionally accredited as training.

A survey on the experience of informed consent, through a questionnaire provided by the associations to their members

The questionnaire had 33 items ranging from the description and evaluation of the patient's latest experience of informed consent to the assessment of what elements they considered most important for a good practice. A total of 736 questionnaires were sent by mail or distributed to patients by hand through their associations within the province of Milan, and 168 were filled and sent back. The aim of this investigation was to collect more

*The associations have always been a historical backbone of the Fondazione Ca' Granda: during a public debate all the patient associations working at the hospital discussed their involvement in the project and then 8 of them joined since the very beginning.

Table 2. Analysis on 753 Consent Forms at the Beginning of the Project: Informative Contents

Informative Contents	No, %	Scarce, %	Some, %	Yes, %
Information about the patient pathology	29.5	23.8	28.2	18.6
Information about the proposed treatment	11.8	36.7	24.9	27
Information about the intended benefits	53.5	25.8	14.7	6
Information about risks	15.3	38	21.5	25.2
Probabilities of success and failure	77.6	11.6	5.8	5
Recovery problems	60.4	25.4	11.2	3.1
Information about the outcomes	43.3	35.7	15.5	5.4
Information about lack of treatment	87.1	4.9	5.3	2.7
Information about alternative options	84.9	8.4	4.1	2.7
Risks and benefits of alternative options	92.7	4.2	1.3	1.7

data about the perception of patients about time, space, languages, and accessibility to information within the local area. Most critical areas that emerged were the scarcity of information given about risks and alternatives and the preference from most patients about detailed and accurate information on both those subjects (Table 3).

Innovating processes, new bodies of good practice

A multidisciplinary committee inclusive of patients, devoted to the governance of informed consent as good practice and denominated "Nucleo Permanente per la Valutazione e il Miglioramento del Consenso Informato" (i.e., Permanent Committee for Improvement and Evaluation of Informed Consent—from now on just "*Nucleo*"), was instituted.

The formal institution of the Nucleo was a decisive stage during the work progress. It was not planned at the beginning but it came as a reasonable and consistent consequence of the ongoing work. If a good practice to be effectively performed has to rely on institutional and organizational conditions, the innovation of the practice itself is likely to imply a certain degree of institutional and

Table 3. Questionnaire About the Present State of the Art: Answers of 168 Patients

Did you receive information about the risks connected with your treatment?			
Yes		No	
76%		24%	
Did you receive information about the alternatives to your treatment?			
Yes		No	
42%		58%	
Would you like the risks connected with your treatment to be described:			
I would like to receive no information on risks	Very generally	Widely but not going into every detail	In a very detailed way
1%	3%	23%	73%
Would you like the alternative to your treatment to be described:			
I would like to receive no information on alternatives	Very generally	Widely but not going into every detail	In a very detailed way
0%	5%	24%	71%

Table 4. Multidisciplinary Committee Composition

Nucleo per la Valutazione e il Miglioramento del Consenso Informato
A representative of the scientific direction
A representative of the sanitary direction
A representative of the nursing services direction
Responsible for risk management or delegate
Responsible for the quality improvement office or delegate
Responsible for the education office or delegate
Responsible for the public relations office or delegate
Responsible for the office of public advocate
An expert in bioethics
An expert in BioLaw
An expert in legal medicine
Representatives from 6 associations of patients and volunteers

Note. All the representatives of patients are invited to the Nucleo meetings. The evaluative activity is shared between them and they alternate at it. A selection of experts is called to contribute on specific issues, ranging from medical specialties to legal matters.

organizational change. Because the practice at stake is a relational, participatory practice, the institutional change will have an open, participatory character. For this reason the Nucleo was designed along the lines of an Ethical Committee for Clinical Practice, composed by 17 permanent members, including six patients' representatives together with clinicians, experts, and hospital managers (Table 4). The Nucleo has been thought as a deliberative space where the decisions about how to evaluate and direct the ongoing process of innovation could be performed in a transparent way, with the contribution of different perspectives and expertises. Moreover, as the process advanced, some members of the Nucleo, which had functions inside the hospital organization, were in charge to actively tutor the clinical units in their work of renewal of procedures and forms.

A new institutional guideline: Collegial logic and quality of care

The new guideline for a good practice of informed consent within the foundation has a wide scope (Table 5). It is made out of different contributions elaborated by

- patients and their associations through the *Vademecum,*
- every unit through a shared analysis of good informative practices, and
- experts and clinicians through the discussion of the multidisciplinary scenarios.

The final draft of the document was read and adjusted by all those who participated in the elaboration of its parts. It was then approved by the Nucleo, distributed to the units and published on the Nucleo Web site to the public as the official document adopted by the hospital as a normative reference for its internal practice.

Good informative practice: A path to share and tailor

The promotion of a good practice of informed consent is through a "participatory" innovation of all consent forms and informative procedures within each clinical unit. The forms were thought as part of a dialogic process, with semi-open content to be tailored to the single patient and contextualized into the unit activity through the measure of the local outcomes of care and benchmarking. This work of renewal of processes and documents within each unit was divided in 2 main stages, the former (1) experimental, the latter (2) meant as a passage from experimental to routine work.

1. During the first stage, every unit was asked to elaborate a new consent form about one of its most common or most critical sanitary acts in a good practice perspective. The elaboration of this "prototype" was supported by a structured format, which held a minimum set of identification elements and informative fields. Every consent prototype was subjected to a deliberative laboratory including on average 1 or 2 clinicians, 2 or 3 patients, and 2 institutional representatives to debate the document with a focus on informative

Table 5. New Institutional Guideline Index

adequacy, comprehensibility of language, and viability within the everyday practice. The patients were involved by invitation to those who were preparing to the sanitary act or going through their follow-up. In the case of very common sanitary acts, such as transfusion and biobanking, instead of actual patients, a group of citizens was involved as volunteers to reflect the wide audience who generally receives that kind of sanitary assistance. This aimed to a double purpose: to verify whether the form was functional to a dialogic process and discuss its logic to privilege patients' understanding.

The outcome of each deliberative laboratory was a modified prototype and a written report about the deliberation process. The renewed prototype was then validated a second time by the Nucleo and then sent back to the unit with a specific report. All the documents produced in the process were stored and made available to the people involved

Table 6. Registered Improvements in Written Information After the Participatory Laboratories With 113 Patients on 43 Consent Prototypes, as Evaluated by the Nucleo

The registered presence of all the requested identification elements and contacts had a relative increment of 22.5%.
The registered presence of quantitative information about risks connected with the treatment had a relative increment of 79%.
The registered presence of quantitative information about probabilities of success of the treatment had a relative increment of 18%.

through a dedicated Web application. This experimental process was intended to have an educational function for the professionals and let them rethink their usual management of informed consent procedures within an open and critical debate. The process involved 53 clinical units and for each one of them at least 1 deliberative laboratory was held and at the end a total of 113 patients and volunteers contributed to it. The results of this evaluation process showed not only significant modification of the informative style and language but also, on average, an increased amount of given data about contacts, risks, and foreseeable outcomes and an overall much better compliance to the institutional good practice standards (Table 6).

2. Once the experimental stage was concluded, every unit started an overall update of their consent forms and procedures with the assistance of a tutor from the Nucleo. This transition from the experimental to the ordinary work implies a complete renewal of practices assuming the participatory perspective shared with patients. For every complex, invasive, unusual, or significantly risky medical act, the unit is required to plan and publish in advance on the project Web site the informative processes in terms of scheduled encounters, responsibilities, and references and to rewrite consent forms and other support tools like texts, images, and electronic resources. To complete the update, the director of every unit is invited to perform a self-evaluation on the outcomes through a given checklist. This enforces a form of participatory audit where the duty of evaluation of the practice is constantly shared between the diffuse activity of clinicians and the supervision of the Nucleo. Some units are, in fact, already planning further evaluative actions that include patients as evaluators of the quality of the information and assistance they received.*

DISCUSSION

This quite demanding approach aims to a good practice of informed consent as a shared decision making (Charles et al., 1997), underlines the need to contextualize the written documentation within the whole informative process (Lidz et al, 1988), and favors an earlier systematization of the outcomes within a Web site that is designed to allow a transparent and interactive management. Because informed consent is a basic element of most clinical practices, this focus on shared informative and decision-making processes effectively favors a concrete planning and implementation of patient-centered clinical settings and is, in fact, already generating other research actions† where patients, clinicians, and managers are together at work on specific clinical settings. Moreover, from a legal point of view, this formalization of the informative process could also open some new perspectives as innovative probative evidence. During a judicial controversy, the availability of a written documentation that, beside the consent form, describes how the information was delivered and discussed with the patient, could in fact significantly shift the attention from the discussion about "how much information was

*A research proposal is in development with pediatric surgery and pediatric anaesthesia to implement a joint evaluation of their renewed informative practices with the involvement of patients and parents.

†It's worth noting at least that in 2009 we started both a project on the participatory design of clinical settings for patients with Cystic Fibrosis and Thalassemia and a working group promoted by the "Nucleo" and devoted to the issue of clinical relationships and informed consent with minors and mature minors.

given" to that about "how effective and articulated was the informative process."

Overall, the most relevant and effective innovations that emerged from the project are the new role of coauthors given to patients and citizens, the opportunity for clinicians to be actively involved in the governance of their institution, and the extension of the participatory approach to institutional representatives and managers beyond the classic scheme, centered on the involvement of patients by clinicians or citizens by policy makers. All together, these elements redefine the applied deliberative method as a participatory method that faces the complexity of clinical practice through the involvement of all the actors as necessary interlocutors (Parker, 2007). The knowledge of a tailored care is a work in progress; it cannot be completely determined in advance because it requires the joint contribution of practical experience, scientific knowledge, and ethical assessment. Thus, each actor discovers himself or herself as author, better said as coauthor. Consequently, the informed consent governance is proposed as an open-ended deliberative space where all these coauthors of the practice play an active role as cooperative priority setters and mutual educators.

In particular, our experience has showed that many citizens acted as creative and effective carriers of innovation, that most professionals were significantly stimulated by this new kind of interactions with their institution and patients, and that institutional representatives were challenged to think innovatively about their action as bottom-up process. For instance, this is supported by the evidence that during the experimental phase patients really played a role as institutional coauthors in defining the standards of the innovated documentation and way of evaluation (Table 6). Moreover, at the level of clinical choices, this logic of coproduction is beginning to promote a better risk management because an informed patient is a better "manager" of his or her own health condition and at the same time is a better information provider to the clinician, thus preventing errors.

A common deliberative process where all parts are involved allows for a greater mutual understanding about how these different perspectives can be reasonably justified and shared between all the actors to bring about a consensual governance of the issues at stake (Gutmann & Thompson, 1996). Managers are in fact pushed to take into account closely which features characterizing an excellent clinical practice but may require some change of both organizational and economical plans. Clinicians and patients, on the other hand, are pushed to reflect about the conditions of a viable good practice, including limited resources, organizational constraints, and long-term strategies, whose necessity may be unclear at first but whose consequences in terms of fairness, sustainability, and innovation are significant in the long run (McKie et al, 2008).

Should be more clear than that this approach, while sharing some characteristics and purposes with the Citizens' Juries (Iredale & Longley, 2007; Lenagan, 1999), is clearly quite different in focusing on the equal and balanced participation of different actors and inaiming to the establishment of long-standing participatory institutional innovations rather than singular, time framed deliberative events. The overall efficacy of this bottom-up, on-the-field research process enforces the assumption not only that the typical kind of knowledge that comes with practical experience is crucial to promote good clinical and informative practices but also that it should be central in defining the features and applications of participatory and deliberative methods. Although the debate about the involvement of citizens and patients in health care practice and planning is lively (Abelson, et al., 2003; Abelson, et al., 2007; Council of Europe, 2000; Gruskin & Daniels, 2008; Litva et al., 2002), it still needs much input coming from concrete applications to define its own forms, justifications, and standards on wide experiential basis (Gagliardi et al, 2008; Nilsen et al, 2006).

CONCLUSIONS

Overall, the project resulted as a very useful laboratory to design an original model of patient participation to the innovation and implementation of good clinical practices. The

research as a bottom-up process moved from real issues to the participatory governance of informed consent intended as an essential feature of good clinical practice. The emerging model can be described as a deliberative process where participation

- involves all the actors of the practice (clinicians, patients, and institution) as equal co-authors within a process of evaluation, innovation, and implementation of good practice;
- is conceived as a central feature of both good clinical practice and institutional governance and means an opportunity of continuing education for all the actors/authors involved because the change in standards, habits, perspectives, and priorities among the participants is an essential part of continuous innovation; and
- favors a viable management of informative processes and clinical settings where actors are more directly engaged and responsible for the evaluation, innovation, and systematization of practices, procedures, guidelines, and documents.

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