Health Information Technology Department
Mashhad University of Medical Sciences

In the name of God

Mashhad University of Medical Sciences

DOES WRITTEN INFORMED CONSENT ADEQUATELY INFORM SURGICAL PATIENTS? A CROSS SECTIONAL STUDY

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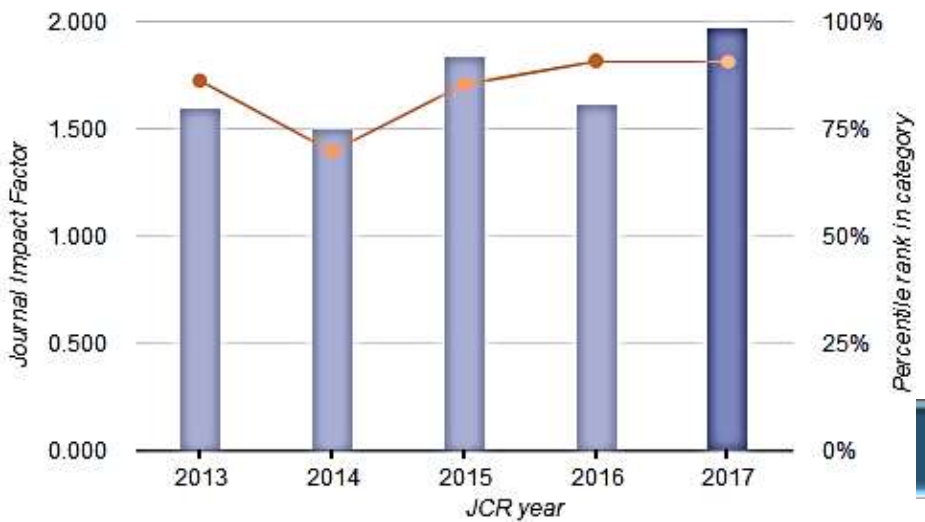

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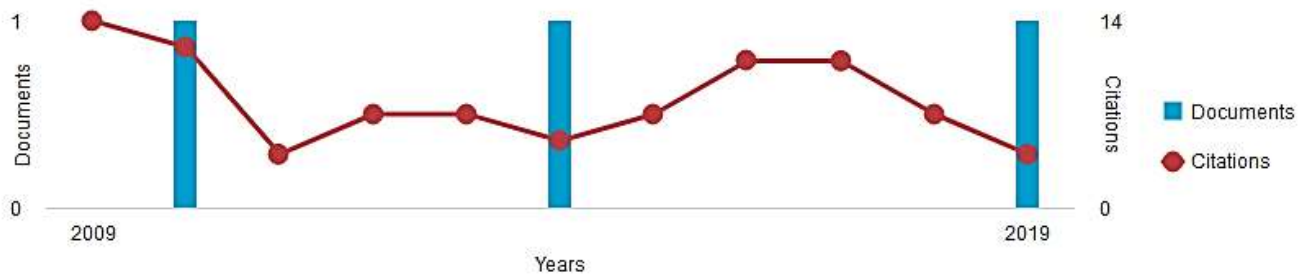

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BACKGROUND

- **Informed consent** (IC) is a process by which a physician interacts with a patient, enabling the latter to make a **knowledgeable decision** regarding the treatment of his or her disease. IC consists not only of the **form** that patients must **read and sign**, it also involves **oral communication** that helps physicians establish a stronger relationship with the patients, which is considered by some to be a **prerequisite** for **well-reasoned** decision-making.

BACKGROUND (Continuation)

- Two distinct but interrelated components characterize IC: the information about risks, benefits and alternatives and consent to undergo the proposed surgical procedure.
- Italian jurisprudence has further broadened the meaning of IC to include information on supplies and equipment— as well as their service records—so that patients can opt to transfer to better-equipped facilities. Despite these guidelines, implementing comprehensive IC is elusive.

BACKGROUND (Continuation)

- Challenges and limitations of IC .
- The four principles of biomedical ethics (autonomy, beneficence, nonmaleficence and justice) are generally taken into account.
- The more pertinent to the ethics of IC is the principle of autonomy for which the person has the right, at all ages and stages of life, to have for himself, choosing whether to accept or refuse the ad, on its health.
- It Is possible only as consequences of an adequate information.

BACKGROUND (Continuation)

- Remain mindful that there are **patients** who will **not to be informed**, who will **not participate in** treatment decisions and who will experience **anxiety** or other negative effects (this is known as "**nocebo effect**"), especially if they become aware of serious side effects due to surgery.

OBJECT

- Explored whether the written IC form was delivered to patients, whether they signed the consent form and whether they read and understood the information about the surgical intervention.

- Investigated verbal communication between patients and physicians and whether it affected patient decision making.

METHODS

- Setting

Epidemiological cross-sectional study_ between January 2016 to June 2016_ to assess the quality of the IC process at nine general hospitals within Italy's Campania Region.

These facilities to ensure representative coverage of the entire region territory as well as the representative participation of different general-hospital typologies. Four of the facilities are known as specialized hospitals (aziende ospedaliere), two are local hospitals (presidi ospedalieri), one is a teaching hospital (azienda ospedaliera universitaria), and two are private hospitals.

METHODS(Continuation)

- Participants and Data Collection

Post surgery adult patients admitted in general surgery and giving the written consent to participate were included in the study. All patients were recruited in general surgery departments and interviewed via a structured questionnaire between the second and the seventh day after surgery, at the end of their first surgical follow up visit.

METHODS(Continuation)

- Children under 18 years of age and patients who required intensive care or were taken back into surgery were excluded.
- Subjects were interviewed by one of four physicians adequately trained. All of them are specialized in Public Health Epidemiology and Hospital Organization, and were independent from the surgical team and from the hospital.
- All the patients were interviewed in a room where their privacy could be ensured, and their answers remained confidential.

METHODS(Continuation)

- Questionnaire

The questionnaire, which was divided into four sections, was formulated after an extensive literature search.

- Section 1: Descriptive characteristics of the study participants (n = 6 questions)
- Section 2: Information on the delivery, signing, reading and comprehensibility of the written IC form (n = 6 questions)
- Section 3: Additional information (acquired orally) on the explanation of the consent and on the effect of the written and oral information (n =11 questions)
- Section 4: Information on the surgery outcome and on the post-surgical period (n = 4 questions)

METHODS(Continuation)

- Sample Size

The sample size was estimated to be at least 400 subjects, assuming a 50% of expected prevalence of the most important variables (delivery, reading and understanding the IC form), with precision of 5% and level of significance of 95%.

METHODS(Continuation)

- Data analysis
  - using **SPSS 21**
  - The **prevalence** of delivery, reading and understanding of IC
  - several **bivariate analysis** were performed to determine whether **socio-demographics** characteristics are in **relationship** with delivery, reading and understanding IC.
  - checked whether patients to whom the IC form had been explained or who had received additional oral information were more **satisfied**. **Stratification analysis** was used when crude **Odds Ratio** (OR) were statistically significant in bivariate analysis.

بیشتر بدانیم

- Odds = $\frac{p(H)}{1-p(H)}$
- Odds ratio = $\frac{odds\ male}{odds\ female}$

- Ho: $OR = 1$ → P –value< 0.05 → R Ho

RESULTS

- Among the 632 patients enrolled _ 72 (11.4%) did not adhere to the survey. remaining 560 participants.

RESULTS(Continuation)

Table 1 Socio-demographics characteristics of patients ($n = 560$)

	n	%
Sex		
Female	365	65.2
Male	195	34.8
Total	560	100.0
Age		
18–40	206	36.8
41–60	161	28.7
61–80	163	29.1
> 80	30	5.4
Total	560	100.0
Marital Status		
Married	385	68.8
Unmarried	104	18.6
Widow /Widower	54	9.6
Separate/Divorced	17	3.0
Total	560	100.0
Education		
Illiterate	5	0.9
Primary School	114	20.3
Middle School	188	33.6
High School	186	33.2
Degree	67	12.0
Total	560	100.0
Nationality		
Italian	539	96.2
Foreign	21	3.8
Total	560	100.0
Surgical Complexity		
Low	82	14.6
Middle	275	49.1
High	203	36.3
Total	560	100.0

65.5 %

85.4 %

RESULTS(Continuation)

Table 2 Modalities of acquisition of written IC ($n = 560$)

	n	%
Have you received a written IC form?		
Yes	473	84.5
I don't know / I don't remember	78	13.9
No	9	1.6
Total	560	100.0
Who signed it?[a]		
Patient	448	94.7
Patient + relative	18	3.8
Relative	5	1.1
Parent	2	0.4
Total	473	100.0
Did you read it?[a]		
Yes	245	51.8
No, I did not want	167	35.3
No, due to lack of time	31	6.6
Partially / Distractedly	30	6.3
Total	473	100.0
Was it understandable?[b]		
Yes	249	90.9
Partially	25	9.1
No	0	0.0
Total	274	100.0
Time before the surgery[a]		
Immediately before	81	17.1
Some hours before	113	24.0
The day before	163	34.5
> 1 day	83	17.5
They can't remember	33	6.9
Total	473	100.0
Who delivered it?[a]		
Operative surgeon	212	44.8
Other surgeon	160	33.8
Nurse	34	7.2
Anesthetist	13	2.8
Administration	2	0.4
I don't remember	52	11.0
Total	473	100.0

[a]including only those who received it
[b]including only those who received and read it

41.1 %

RESULTS(Continuation)

Table 4 Type of oral information delivered by physician ($n = 560$)

	n	%
Diagnosis	520	92.8
Type of surgery	494	88.2
Prognosis	416	74.2
Post-operative progress	384	68.6
Benefits of surgery	381	68.0
Outcome of non treatment	362	64.6
Alternatives to the proposed surgery	354	63.2
Chances of success of the surgery	346	61.8
Potential complications of the surgery	300	53.6

RESULTS(Continuation)

Table 7 Relationship between reading written IC with age and education level of patients and Mantel-Haenszel test (M.H)

		Yes/Total	Reading %
Age	> 60	50/155	32.2
	≤ 60	194/316	61.4
	Total	244/471	51.8

OR = 3.33 (CI 95%: 2.22–5.01) $p = 0.000$

Education	< High School	102/247	41.3
	≥ High School	142/224	63.4
	Total	244/471	51.8

OR = 2.46 (CI: 1.70–3.57) $p = 0.000$

Mantel-Haenszel test

Age > 60	Education		
	< High School	30/112	26.8
	≥ High School	20/43	46.5
	Total	50/155	32.3

OR = 2.37 (CI 95%: 1.14–4.92) $p = 0.001$

Age ≤ 60	Education		
	< High School	72/135	53.3
	≥ High School	122/181	67.4
	Total	194/316	61.4

OR = 1.81 (CI 95%: 1.14–2.86) $p = 0.001$

M.H. test stratified for age OR = 1.94 (C.I.1.32–2.90) $p = 0.001$

RESULTS(Continuation)

Table 8 Relationship between patients satisfaction (not satisfied/satisfied) and oral explanation of IC form

Oral explanation of ICform	Not satisfied n / %	Satisfied n / %	Total	O.R.	C.I. 95%	*p*
Not explained	25 / 15.6	135 / 84.4	160	**1,00**		
Explained	30 / 8.4	329 / 91.6	359	**2,03**	1,15-3,58	0,01
Total	55 / 10.6	464 / 89.4	519			

DISCUSSION

- Complete information before an invasive procedure is an ethical requirement, and it is very important to involve the patient in decision-making regarding the treatment. Well-informed patients are generally more satisfied and file fewer legal claims .
- four elements contributing to correct utilization of written IC forms: delivery, signature, reading and comprehensibility.

DISCUSSION(Continuation)

- main shortcoming of the written IC process has been that almost all patients received and signed it, but only half of them read it adequately.

Possible reasons for the findings are:

- first, many patients showed scarce interest in the IC document
- Secondly, surgeons might have shown a lack of interest in the document
- Thirdly, almost half the patients received the form immediately or just a few hours before the surgical procedure

DISCUSSION(Continuation)

The main **limitation**

- potential **recall bias** because the information was obtained through face-to-face interview many days **after** the delivery of the written IC
- The patients satisfaction has **not** been collected as **direct question**, but has been evaluated as surrogate variable, **interpreting** the answer to a different question.
- patients who had required **intensive care** or had been brought **back** into surgery were excluded. the results would **not** be **generalized** to patients in more severe settings.

CONCLUSION

- Written IC is **essential** in medicine in order to ensure that patients **have** the needed information to make an **aware choice** and **consenting** to treatment.
- In our experience, **written information** has **not** provided patients with **adequate** decision-making tools for imminent health matters, while pre-operative **oral information** was **better** suited to meet patients' needs.
- Finally, it is necessary that **physicians** also enhance their **communication skills** to enable them to build alliances with patients in order to become **effective partners** Because of this, we must implement **communication training**

CONCLUSION(Continuation)

- This must be incorporated into training at **all levels**, including **postgraduate** medical programs, in order to improve physicians' **listening skills** and develop **interactive communication skills**.
- Such a **trained physician** can help patients in defining what is the **best choice** to make in order to **improve** their own health status.
- This seems to be the main way to ensure patients' "**self-determination**" in health care.

Thanks for Your Attention

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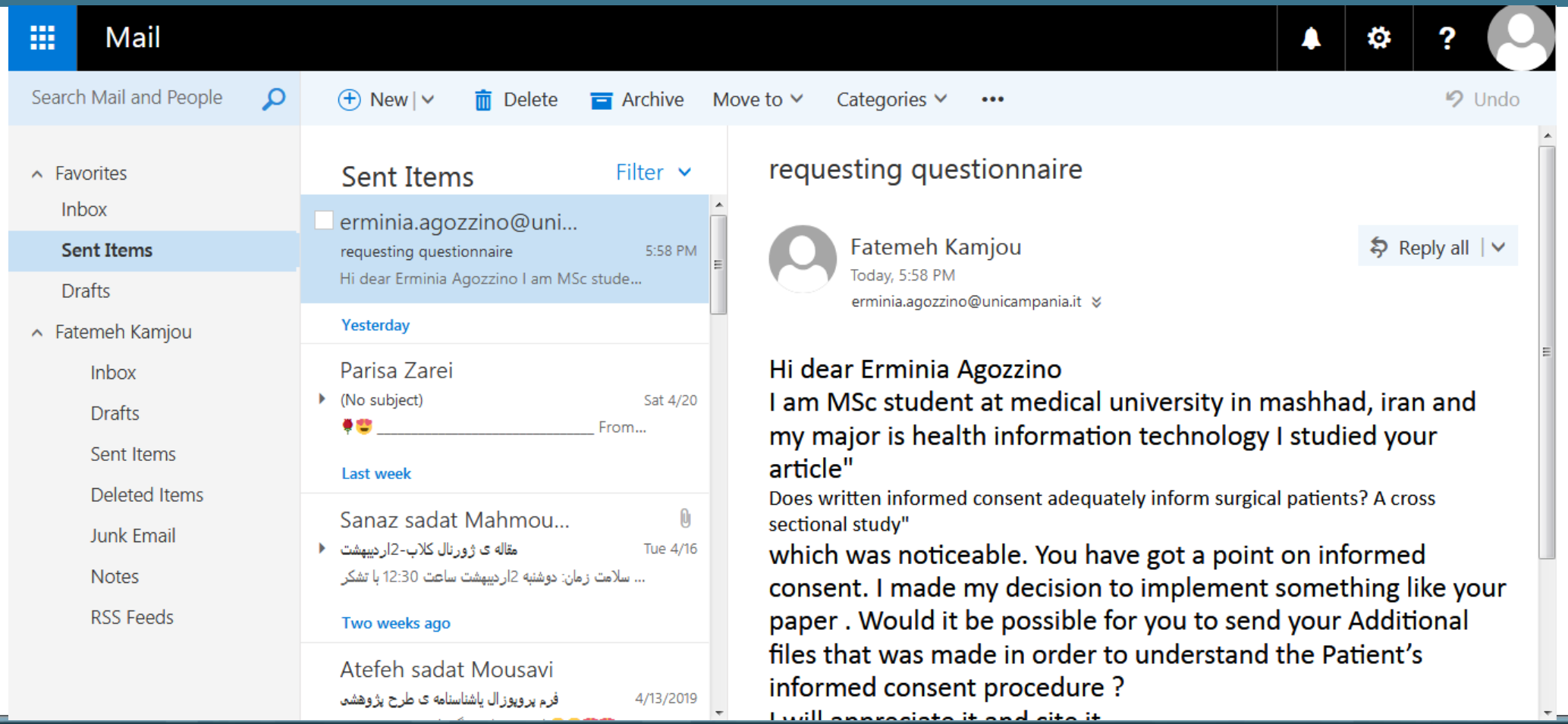
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which was noticeable. You have got a point on informed consent. I made my decision to implement something like your paper . Would it be possible for you to send your Additional files that was made in order to understand the Patient's informed consent procedure ?