#### **COMPUTER APPLICATIONS**



# Dematerialisation of patient's informed consent in radiology: insights on current status and radiologists' opinion from an Italian online survey

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#### **Abstract**

**Purpose** To assess the current status of patient's informed consent (PIC) management at radiological centres and the overall opinion of radiologist active members of the Italian Society of Medical Radiology (SIRM) about PIC dematerialisation through an online survey.

**Methods and materials** All members were invited to join the survey as an initiative by the Imaging Informatics Chapter of SIRM. The survey consisted of 11 multiple-choice questions about participants' demographics, current local modalities of PIC acquisition and storage, perceived advantages and disadvantages of PIC dematerialisation over conventional paper-based PIC, and overall opinion about PIC dematerialisation.

**Results** A total of 1791 radiologists (amounting to 17.4% of active SIRM members for the year 2016) joined the survey. Perceived advantages of PIC dematerialisation were easier and faster PIC recovery (96.5%), safer storage and conservation (94.5%), and reduced costs (90.7%). Conversely, the need to create dedicated areas for PIC acquisition inside each radiological unit (64.0%) and to gain preliminary approval for the use of advanced digital signature tools from patients (51.8%) were seen as potential disadvantages. Overall, 94.5% of respondents had a positive opinion about PIC dematerialisation. **Conclusion** Radiologists were mostly favourable to PIC dematerialisation. However, concerns were raised that its practical implementation might face hurdles due to its complexity in current real life working conditions.

**Keywords** Informed consent · Dematerialisation · Online survey · Paperless

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## Introduction

Dematerialisation is a complex process involving the development of a digital document flow with full legal value aimed to support and, in perspective, replace conventional document production and archiving for public or private activities [1-12]. Historically, the development of Radiology Information System (RIS) and Picture Archiving and Communication System (PACS) networks dating back to the end of last century marked a seminal step for dematerialisation of radiological data, followed on a larger scale by the gradual integration of clinical documents from individual patients into a single digital document (i.e. the electronic health record). The advantages of digitisation over paper- and film-based workflow in radiology have been widely demonstrated [13–17], and attempts have since been made to extend the process to administrative key areas of healthcare data management, including, on a national level, the introduction of the digital medical recipe in most Italian regions [3–12]. However, to our knowledge, no systematic initiatives have been taken so far towards dematerialisation of patient's informed consent (PIC) for diagnostic and interventional radiology procedures, despite incentives from international [1, 2] and national government agencies and healthcare institutions to promote digitisation in the public administration as well as in the healthcare system [3–12]. Such delay is due to the need for dematerialised PIC to be formally equivalent to its conventional, paper-based version, implying for it to fully conform to current laws and privacy regulations, ensure proper patient's understanding of medical procedures for which written informed consent is required, and provide seamless integration with existing RIS/PACS infrastructure at radiological centres [18, 19]. While the development of a fully functional programme for PIC dematerialisation may pose significant legal and technical challenges, evidence exists in the literature that PIC dematerialisation with the aid of portable devices is feasible and as effective or superior to conventional methods in several aspects [20–24].

The Italian Society of Medical Radiology (SIRM) has promoted the development of guidelines for PIC dematerialisation and has put the Imaging Informatics Chapter and Informed Consent Commission of SIRM in charge for its implementation. In this context, we sought to gain insight about the current modalities of PIC acquisition for radiological procedures in Italy and the opinion of Italian radiologists about PIC dematerialisation via an online survey.

## Materials and methods

The online survey was launched as part of an initiative by the Imaging Informatics Chapter of SIRM aimed to promote dematerialisation of PIC for radiological procedures (both diagnostic and interventional), in cooperation with a number of IT firms. Our survey was aimed to get an overview of the current modalities of PIC acquisition and storage at radiological centres, as well as to know the overall opinion of radiologists about PIC dematerialisation and its perceived potential advantages and disadvantages over conventional paper-based PIC.

A radiologist member of the Imaging Informatics Chapter of SIRM (F.C.) created the online survey using the Survey-Monkey platform (www.surveymonkey.com). The survey was devised following suggestions from a multidisciplinary expert panel of SIRM and consisted of 11 questions, of which 9 were single choice and 2 multiple choice ("Appendix"). A free text field was left at the bottom of each question for additional comments.

Based upon a similar approach to two previous SIRM surveys on teleradiology and radiological structured reporting [25, 26], every single SIRM member received a personal email invitation to join the survey via a direct web link from the President of the SIRM Imaging Informatics Working Group. The questionnaire could be accessed only once by each member and was kept online for 11 days. Two reminders were sent one week after the survey's opening and on the final day, respectively.

Data were analysed quantitatively using SurveyMonkey Statistical Tool and dedicated software for statistical analysis (GraphPad Prism v. 7, www.graphpad.com). The correlation between age (as determined by Question #2) and rate of PIC dematerialisation supporters (Question #11) was assessed using the Spearman rank test. Furthermore, the association between demographic characteristics other than age (i.e. geographic distribution, workplace and job position, and self-assessed IT skills as determined by Questions #1, #3, #4 and #5, respectively) and rate of PIC dematerialisation supporters was evaluated using the Chi-square test. A *p* value less than 0.05 indicates statistical significance.

## Results

A total of 1791 SIRM members in full standing for the year 2016 took part in the survey (Table 1). The geographic proportion of respondents relative to the number of members per region was comparable across the various Italian regions (Question #1). Also the age distribution (Question #2) of respondents was quite homogeneous, with two peaks in the 36–45 years old and the 56–65 years old ranges [25.5% (449/1769) and 25.7% (453/1769), respectively].

55.0% (975/1774) of respondents worked at public non-academic hospitals, whereas 22.4% of them (398/1774) operated privately and 17.0% (302/1774) were employed at University hospitals (Question #3). In absolute terms, most respondents worked as basic level professional assistant





Table 1	Distribution of replies
to Quest	tions from #1 to #8

Q1—Geographic distribution	Northern Italy (721/1773, 40.7%) Central Italy (504/1773, 28.4%) Southern Italy and Islands (548/1773, 30.9%)					
Q2—Age distribution <sup>a</sup>	26–35 yo (386/1764, 21.9%) 36–45 yo (449/1764, 25.5%) 46–55 yo (364/1764, 20.6%) 56–65 yo (453/1764, 25.7%) over 65 yo (112/1764, 6.3%)					
Q3—Site of main professional activity	Public hospital (975/1774, 55.0%) Private hospital (168/1774, 9.5%) University hospital (302/1774, 17.0%) Research institute (56/1774, 3.1%) Private radiology practice (230/1774, 13.0%) Other (43/1774, 2.4%)					
Q4—Professional degree	Resident (222/1780, 12.5%) Consultant (301/1780, 16.9%) Assistant Medical Director (temporary position) (124/1780, 7.0%) Professional Assistant Medical Director (basic level) (423/1780, 23.7%) Professional Assistant Medical Director (advanced level) (256/1780, 14.4%) Simple Unit Director (133/1780, 7.5%) Complex Unit Director (153/1780, 8.6%) Academic Researcher (19/1780, 1.1%) Associate Professor (22/1780, 1.2%) Full Professor (12/1780, 0.6%) Other (115/1780, 6.5%)					
Q5—Self-assessed computer skills	Excellent (224/1778, 12.6%) Good (1207/1778, 67.9%) Barely sufficient (332/1778, 18.7%) Poor (15/1778, 0.8%)					
Q6—Developer of PIC form <sup>b</sup>	Local institution (1311/1702, 77.0%) SIRM (655/1702, 38.5%) Regional Health Department (180/1702, 10.5%)					
Q7—PIC revocation	Yes (1105/1772, 62.3%) No (421/1772, 23.8%) Don't know (246/1772, 13.9%)					
Q8—PIC storage <sup>b</sup>	Paper-based, in-hospital archive (1428/1726, 82.7%) Paper-based, out-of-hospital archive (119/1726, 6.9%) Digital, RIS/PACS (117/1726, 6.8%) Don't know (161/1726, 9.3%)					

Percentages were calculated out of the total number of replies to each question. <sup>a</sup> years old. <sup>b</sup> Multiple answers allowed

medical directors [23.7% (423/1780)] or consultants [16.9% (301/1780)], respectively (Question #4).

The majority of responders deemed their IT skills good [67.9% (1207/1778)] or excellent [12.6% (224/1778)], whereas a minority declared to have barely sufficient [18.7% (332/1778)] or poor [0.8% (15/1778)] IT skills, respectively (Question #5).

PIC forms were mostly developed locally at each survey participant's institution [77.0% (1311/1702)] or, less frequently, by SIRM [38.5% (655/1702)] or the Health Department of each region [10.5% (180/1702)] (Question #6).

PIC could be revoked by the patient anytime before the examination according to 62.4% (1105/1772) of survey

respondents (Question #7), and PIC forms were mainly stored in the hospital archive [82.7% (1428/1726)] or, much less frequently, outside of the hospital [6.9% (119/1726)] or were digitally archived into the RIS [6.8% (117/1726)] (Question #8).

The main advantages of dematerialised PIC over conventional, paper-based PIC as perceived by the survey respondents (Question #9) were its easier and faster recovery [96.5% (1669/1729)], safer storage and conservation [94.5% (1643/1738)], reduced cost due to the workflow going paperless [90.7% (1573/1735)], higher degree of protection in case of medico-legal litigation [83.8% (1439/1717)], and simplified patient identification and registration [74.3%



(1274/1714)] (Table 2). On the other hand, the main disadvantages to PIC dematerialisation (Question #10) were the need for dedicated areas to be created inside each radiological unit for dematerialised PIC collection on portable devices (such as tablets) [64.0% (1106/1729)], and its overall complexity due to obtaining preliminary approval for the usage of advanced digital signature from each patient, which could be time consuming [51.8% (898/1735)] (Table 3).

Overall, 94.5% of respondents were favourable to PIC dematerialisation, of whom 49.3% were strongly favourable (Question #11) (Fig. 1). No statistically significant correlation was found between survey participants' age and rate of PIC dematerialisation supporters ( $r_s = -0.3$ , p > 0.05). Moreover, no statistically significant association was found between rate of PIC dematerialisation supporters on one hand, and their geographic distribution, workplace, and job position on the other hand (p > 0.05). Of note, although the degree of self-assessed IT skills was lower with increasing age of the survey participants (ranging from 88.5% of good or excellent IT skills in the 26–35 years old group down to

63.9% over 65 years old), age-adjusted rates of PIC dematerialisation supporters were significantly higher than age-adjusted rates of good or excellent IT skills (p < 0.0001). The overall rate of PIC dematerialisation supporters was consistently higher than 90% independent of age (Fig. 2).

# **Discussion**

To the best of our knowledge, this is the first survey on PIC dematerialisation addressed to all members of a national radiological society in Europe.

Similar to the SIRM survey on radiological structured reporting [26], the age and geographic distribution of the survey participants were quite homogeneous and the response rate for each survey question equalled or exceeded 95% for all questions, revealing a general interest in PIC dematerialisation across several generations of radiologists. Such interest and the overall opinion of responders about the current status and future perspectives of PIC

Table 2 Main advantages of dematerialised versus conventional PIC as perceived by the survey participants

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	Total	Average
Simplified patient identification and registration	57 (3.33%)	185 (10.79%)	198 (11.55%)	868 (50.64%)	406 (23.69%)	1714	3.81
Safer PIC storage and conservation	11 (0.63%)	28 (1.61%)	56 (3.22%)	898 (51.97%)	745 (42.87%)	1738	4.35
Reduced risk of PIC loss	12 (0.70%)	37 (2.15%)	58 (3.36%)	831 (48.20%)	786 (45.59%)	1724	4.36
Easier and faster PIC recovery	6 (0.35%)	17 (0.98%)	37 (2.14%)	864 (49.97%)	805 (46.56%)	1729	4.41
Greater protection in case of medico-legal litigation	24 (1.40%)	93 (5.42%)	161 (9.38%)	798 (46.48%)	641 (37.33%)	1717	4,13
Improved patient-doctor communication	53 (3.11%)	342 (20.08%)	507 (29.77%)	554 (32.53%)	247 (14.50%)	1703	3.35
Better communication among administrative operators, radiographers and radiologists	39 (2.29%)	200 (11.76%)	472 (27.76%)	707 (41.59%)	282 (16.59%)	1700	3.58
Lower costs due to paperless operation	18 (1.04%)	25 (1.44%)	119 (6.86%)	734 (42.31%)	839 (48.36%)	1735	4.36
Possibility to statistically analyse data	9 (0.52%)	24 (1.40%)	199 (11.60%)	827 (48.19%)	657 (38.29%)	1716	4.22

Table 3 Main disadvantages of dematerialised versus conventional PIC as perceived by the survey participants

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	Total	Average
Obtaining preliminary approval (consent) for the use of advanced digital signature from each patient may be time consuming	81 (4.67%)	473 (27.26%)	283 (16.31%)	724 (41.73%)	174 (10.03%)	1735	3.25
Dedicated areas should be created inside each radiological unit to collect dema- terialised PIC on portable devices (e.g. tablets)	58 (3.35%)	301 (17.41%)	264 (15.27%)	864 (49.97%)	242 (14%)	1729	3.54
Obtaining dematerialised PIC can be time consuming	87 (5.07%)	580 (33.80%)	334 (19.46%)	578 (33.68%)	137 (7.98%)	1716	3.06
Mistrustful attitude of patients	68 (3.97%)	525 (30.65%)	370 (21.60%)	631 (36.84%)	119 (6.95%)	1713	3.12
Mistrustful attitude of health operators	128 (7.54%)	709 (41.76%)	407 (23.97%)	391 (23.03%)	63 (3.71%)	1698	2.74



**Fig. 1** Rate of replies to Question #11

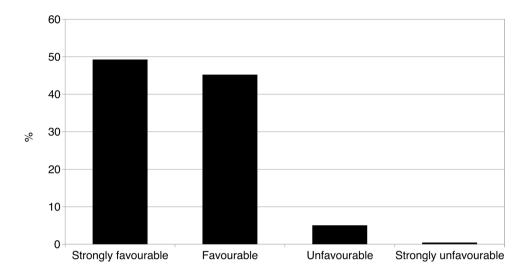
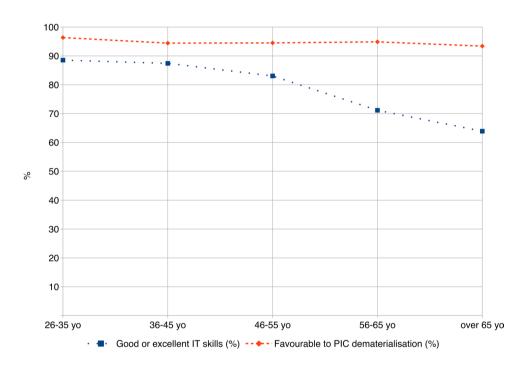


Fig. 2 Rate of survey participants' self-assessed good or excellent IT skills versus rate of PIC dematerialisation supporters in the various age groups. yo = years old



dematerialisation were further substantiated by their selfassessed good IT skills, which are obviously a prerequisite for a satisfactory understanding of the topic.

As a matter of fact, PIC resulted to be mostly obtained on paper forms that are stored in the hospital archive (82.7% of replies to Question #8), whereas it is digitised and archived into the RIS in a small minority of cases (6.8%). This latter circumstance may be due to different factors, including the current lack or inadequacy of technical infrastructures for digital PIC collection (including tablet devices running ad hoc software and connected to dedicated hospital wireless networks) and/or of integration with existing RIS/PACS environments, in spite of substantial investments into dematerialisation by government agencies. Besides, some

features of conventional, paper-based PIC acquisition have emerged from the survey that should be incorporated in a dematerialised, digital PIC version, including the possibility for patients to revoke their consent anytime before radiological procedures (Question #7). In other terms, such basic aspects of conventional PIC should be taken into account and preserved in the design and practical implementation of dematerialised PIC solutions in order to maintain their legal validity, so that the transition from conventional to dematerialised PIC should not substantially alter workflow. Furthermore, the current, more frequent usage of PIC forms developed locally (77.0% of respondents to Question #6) rather than by regional health departments (10.5%) or, better, national scientific societies such as SIRM (38.5%) could be



a potential, yet surmountable hurdle to standardisation and large-scale setup of dematerialised PIC tools. These latter would actually benefit from the adoption of a single, predefined validated PIC model for each radiological procedure, which could also be advantageous for data mining purposes and eventually in case of medico-legal issues [27–31].

Overall, the majority of survey respondents were favourable to PIC dematerialisation and acknowledged several advantages of digital over conventional PIC, the main ones being easier and faster data retrieval, safer data storage, and reduced running costs. In this perspective, tablet-based methods for PIC collection have shown to be preferred over conventional PIC by both patients and medical staff and has proven more effective at ensuring adequate patients' understanding of medical procedures and research trials [20–24, 32, 33]. Interestingly, our finding of a rate of PIC dematerialisation supporters consistently higher than 90% across all age classes of survey participants (independent of and greater than their self-assessed IT skills) may suggest that radiologists are confident about the usability of digital PIC and/or believe that its advantages would outweigh any potential difficulties related to its use as a routine working tool.

On the other hand, the main potential drawbacks of PIC dematerialisation as pointed out in the survey were related to technical difficulties in carrying out the process in real working environments. Technical and organisational issues had also been highlighted as potential disadvantages to widespread adoption of radiological structured reporting in a previous SIRM survey [26]. Actually, tablet-based PIC acquisition resulted to be more time consuming than paper-based PIC collection [21, 24], and earlier work by Haller et al. [34] cautioned against the use of palmtops for electronic data collection in clinical research due to a significant increase in data entry time and risk of typing errors and missing data in comparison with paper-based questionnaires. More recently, Schlechtweg et al. [21] found a positive correlation between the duration of electronic iPad-based briefings and patient age, paralleled by a negative correlation between patient age and computer skills, but nonetheless the majority of patients would prefer iPad briefings to conventional written informed consent forms in the future. Similarly, Rowbotham et al. [24] showed that the time spent for reviewing paper PIC was significantly less than that needed to review iPad-based PIC (13.2 min vs 22.7 min), but the iPad presentation combined more elements (i.e. an introductory video, consent form, and interactive quiz) and gained slightly more user satisfaction and enjoyment compared with conventional PIC. Even more specifically, it has been suggested that the higher degree of understanding and overall satisfaction provided by tabletbased PIC may improve adhesion to clinical trials [23].

A limitation of our study is the relatively small number of SIRM members joining the survey (1791/10304, corresponding to 17.4% of all active SIRM members in full

standing for the year 2016), which could restrict the validity of our findings to a minority of all members. However, the participation rate to our survey was slightly higher than two recent online surveys involving SIRM members on teleradiology [16.5% (1599/9662)] [25] and radiological structured reporting [12.1% (1159/9560)] [26], and much higher than a similar European online survey on teleradiology (368 radiology professionals from 35 European countries) [35], confirming that PIC dematerialisation has gained significant interest within the radiological community.

## **Conclusions**

Our findings show that the majority of radiologist members of SIRM involved in the survey were favourable to PIC dematerialisation. Though most of them were aware of the potential long-term advantages of PIC dematerialisation over conventional, paper-based PIC (mainly related to greater ease, speed, and safety of data collection, storage and retrieval), concerns emerged about potential technical and organisational hurdles that its practical implementation may pose, including the need for extra space and time for digital PIC collection (which would add to regular radiologists' workload), authorisation to use patients' advanced digital signature, and to cater for patients who wish to remain anonymous. Such issues should be factored in and addressed for the planning, engineering, and setup of a large-scale programme for PIC dematerialisation in radiology.

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## Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

**Ethical approval** This article does not contain any studies with human participants or animals performed by any of the authors.

# **Appendix**

- Q1) Which Italian region do you work in?
- Q2) What is your age?
- Q3) What is the site of your main professional activity?
- Q4) What is your professional degree?
- Q5) How would you qualify your computer skills?
- Q6) Who developed the PIC form that you currently use? (multiple answers allowed)
- Q7) Can PIC be revoked by the patient before the procedure?





- Q8) How is PIC usually stored? (multiple answers allowed)
- Q9) The main goal of PIC dematerialisation is to develop a digital document with full legal value that will ultimately replace conventional, paper-based PIC. This process requires patients to approve the acquisition of advanced electronic signature, and radiologists to use digital signature systems as well (e.g. smart card, token, etc.) to countersign PIC. In your opinion, what are the main advantages of PIC dematerialisation?
- Q10) In your opinion, what are the main disadvantages of PIC dematerialisation?
- Q11) Dematerialisation is a process on which the Italian government has invested heavily. "Digital Italy" would allow savings around 43 billion euro per year. Considering the overall issues involving your professional activity, do you believe this process would be needed?

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