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ABSTRACT

The principles of autonomy and informed consent dictate that patients who undergo a radiological examination should actually be informed about the risk of diagnostic errors. Implementing such a policy could potentially increase the quality of care. However, due to the vast number of radiological examinations that are performed in each hospital each day, financial constraints, and the risk of losing trust, patients, and income if the requirement for informed consent is not imposed by law on a state or national level, it may be challenging to inform patients about the risk of diagnostic errors. Future research is necessary to determine if and how an informed consent procedure for diagnostic errors can be implemented in clinical practice.

1. Introduction

Diagnostic errors are common. According to the scientific literature, the retrospective error rate among radiologic examinations is approximately 30%, and real-time errors in daily radiology practice average 3–5% [1]. Strategies to counteract or minimize the potential for misdiagnosis have been discussed in the literature [1–6], but they cannot eradicate the risk of diagnostic errors, even the "best" radiologist is not invincible in this respect [7]. Although the majority of diagnostic errors would probably not cause any patient harm, a proportion does. Data from the United States between 1991 through 2005 showed that 7% of all radiologists faced a malpractice claim each year, of which approximately one-sixth of claims resulted in a payment to a plaintiff [8]. These data suggest that the incidence of diagnostic errors with adverse effects on patient outcome is non-negligible, to say the least [8].

Informed consent has been defined as "consent by a patient to a surgical or medical procedure or participation in a clinical study after achieving an understanding of the relevant medical facts and the risks involved" [9]. The history, principles, and controversies of informed consent have been discussed in several previous works [10,11]. Informed consent is considered a legislative prerequisite for health care, and applies to all treatments and invasive tests, including interventional radiology procedures. However, obtaining informed consent for noninvasive diagnostic imaging examinations (such as radiography, ultrasonography, CT, MRI, and nuclear medicine studies) is still a gray zone [12]. In the majority of examinations, the risk involved is regarded low, and implied consent (i.e. implicitly granted permission by the patient) is considered sufficient [13]. Nevertheless, there is some discussion whether express consent (i.e. explicitly granted permission by the patient, either verbally or in writing) should be obtained before intravenous contrast agent administration and examinations that use ionizing radiation [12,14]. Express consent is now more frequently obtained before CT and MRI in pregnant women [14], and in some institutions it is standard practice to obtain written informed consent for diagnostic imaging studies in all patients, particularly in the outpatient and private practice setting [12]. Literature on informed consent practices for diagnostic imaging in different countries is lacking. However, to the best of our knowledge, current informed consent procedures for diagnostic imaging studies, if applied at all, do not explicitly cover diagnostic errors.

In this communication, we discuss the pros and cons of informing patients about the risk of diagnostic errors, indicate future research directions, and provide our own views.

2. Informing patients about the risk of diagnostic errors: pros

There are several potential advantages of informing patients about the risk of complications due to misdiagnosis. First, it respects the principles of autonomy and informed consent; patients will not be put at risk of suffering from an adverse outcome of which they were not aware. Second, lack of informed consent can reinforce a claim of medical malpractice or serve as an alternative point of attack when the case is otherwise weak [15]. Previous research in other fields of medicine has shown that deficient informed consent is an important reason for

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litigation, and that success chances in informed consent related claims and complaints are high [16,17]. Therefore, it can be argued that an informed consent procedure for diagnostic errors may perhaps also decrease the number of malpractice claims. If the frequency of malpractice claims can indeed be reduced with such a policy, defensive medicine practices by radiologists (e.g. by recommending unnecessary additional imaging) may perhaps also decrease, which would reduce costs. Finally, informing patients of diagnostic errors and their consequences may increase the public's awareness of a radiologist's work and its importance, and society may push policymakers to ensure that all requirements are met for radiologists to deliver high-quality care (including maintaining a healthy balance between staff and workload [1–6]). This will not completely eliminate the risk of diagnostic error, but is likely to reduce its incidence.

3. Informing patients about the risk of diagnostic errors: cons

Acquiring patient consent for diagnostic errors would require significant additional manpower considering the numerous radiological examinations that are performed in each hospital each day. This may be considered unpayable and not a priority for health care systems. Whether or not it would suffice to inform the patient by only adding a paragraph about diagnostic errors to the patient brochure or the radiology report itself, remains a point of discussion [18]. Another issue is that unlike interventional radiology for which it is generally clear which procedure-specific complications can be expected (e.g. bleeding and infection for percutaneous image-guided biopsy), this may not always be the case for a diagnostic imaging test. A potential disadvantage of informing patients about the risk of diagnostic errors is that it may decrease their trust in a hospital and radiology department. No hospital or radiology department would be willing to put its reputation at stake and lose patients and income. It can also be argued that patients would not understand why diagnostic errors are made, because a misdiagnosis is usually (retrospectively) visible; the proof is there. Some patients may also be worried about false negative and false positive results after informed consent about diagnostic errors, and may perhaps not accept to undergo an imaging study which may cause diagnostic delay (although it can also be argued that this is the patient's own decision in line with the principle of autonomy). Finally, patients who question the accuracy of the interpretation of their radiological examination because of their knowledge of diagnostic errors may ask for a double reading, which increases health care costs while it does not change diagnosis in the far majority of cases [19].

4. Future research directions

In order to answer the question of whether or not patients should be informed about the risk of diagnostic errors, more research is needed. First, given the current era of patient-centered medicine, studies need to be performed to investigate patients' preferences. These studies should include the effect of patient characteristics (e.g. age, gender, education), diagnostic error variables (e.g. absolute risk of diagnostic errors and associated complications, and severity of these complications), and health care costs on their preferences. Second, studies are needed to determine the above-mentioned diagnostic error variables in different settings (e.g. CT of the chest and abdomen), because currently available data are limited to gross estimates and older retrospective studies [1]. Third, studies need to be performed to determine the most optimal way how patients can be informed of the risk of diagnostic errors (e.g. written and/or verbal provision of information, by whom and when, implied consent or express consent), taking into account patients' preferences, ethical and legal aspects, and costs.

5. Authors' views

We believe patients should be informed about the risk of diagnostic errors. The most pragmatic approach to achieve this is probably by adding a paragraph about diagnostic errors to the patient brochure of the imaging study the patient is scheduled to undergo. This text passage should describe that their imaging study is being performed in line with (inter)national guidelines when available and interpreted by certified radiologists. The purpose of the examination is to increase or decrease the suspicion of the presence of certain disease(s). The risk of relevant diagnostic errors seems relatively low based on currently available evidence. However, due to the human nature of the work, there is still a chance that diagnostic errors can be made, namely missed diagnosis and wrong diagnosis, which may result in delayed or wrong treatment. The patient may then sign the accompanying consent form of being informed of the risk of diagnostic errors and hand it in prior to undergoing the imaging study. Alternatively, the referring physician may make a note in the electronic patient files that the patient has consented to undergo the imaging study and has accepted the risk of diagnostic errors. Note that we believe verbal consent to be insufficient in light of any malpractice claims. Finally, it should be emphasized that this paragraph represents the opinion of the authors, who are all radiologists. Further research is required, which should particularly involve patients but also referring physicians, and legal and ethical experts.

CRediT authorship contribution statement

Ömer Kasalak: Conceptualization, Writing – original draft, Writing – review & editing. **Jan P. Pennings:** Writing - review & editing. **Jeroen W. Op den Akker:** Writing - review & editing. **Derya Yakar:** Writing - review & editing. **Thomas C. Kwee:** Conceptualization, Writing - original draft, Writing - review & editing.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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