REVIEW

Paediatric cardiac catheterization: An information sheet

Cathétérisme cardiaque pédiatrique : brochure d’informations

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Summary The need to inform patients using validated scientific data is acknowledged internationally. The obligation to inform patients is based on a fundamental principle of French law: the principle of the unavailability of the human body. Before engaging in diagnostic or therapeutic strategies such as paediatric cardiac catheterization, the healthcare professional must explain the disease, the advantages and drawbacks of each treatment strategy and their foreseeable benefit/risk ratio in order to help older children and their parents come to a decision. To obtain this required consent and before the care is provided, the infant and their legal representative must have received clear, accurate and understandable information. An information sheet cannot substitute for verbal information. Guidelines for good practices on the delivery of information have been established by the Health Authorities and officially recognized in a decree from the Ministry of Health. These documents allow professionals to draft a written information document for patients and healthcare users. This document must help the patient to take part in decisions that concern them. The law of 4th March 2002 regarding the rights of patients and the quality of the healthcare system states that ‘in cases of litigation, it is the responsibility of the professional or the healthcare establishment to provide proof that the information was given to the person concerned in the conditions set out in the present article. This proof can be brought by any means’.

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Abbreviations: ALARA, As low as reasonably achievable; BW, Body weight; CC, Cardiac catheterization; DNA, Deoxyribonucleic acid; HAS, Haute Autorité de santé; PHC, Public health code.
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Introduction

The incidence of congenital heart disease is less than 1%. Overall, three out of 1000 live births will have congenital heart disease that will require an immediate intervention, including cardiac catheterization (CC) and surgery [1]. CC should be used in any circumstance in which the anatomy of the heart of a child with congenital heart disease is inadequately defined by non-invasive means. On some occasions, particularly in very complex lesions, more specific details about the anatomy or haemodynamic features are necessary. Paediatric CC is a safe and effective procedure used to obtain detailed information about heart anatomy as well as to repair the heart without surgery. Advances in non-invasive imaging have allowed CC to become increasingly a catheter-based therapeutic option rather than a diagnostic tool. Paediatric CC has evolved to include a variety of interventional procedures, including the closure of atrial septal defect, the closure of ventricular septal defect, the closure of patent ductus arteriosus, the creation of holes such as septostomy, angioplasty, valvuloplasty, the placement of stents to open up narrowed vessels, the embolization of vessels such as collateral vessels or, more recently, the replacement of heart valves [2—5].

Paediatric CC is not without risk to the patient. In the last decade, there have been significant improvements in technology and equipment. Nonetheless, the risk of complications remains and these risks adversely affect outcomes. Healthcare professionals have to explain to patients/parents why they intend to carry out a particular diagnostic test or a procedure, such as CC. We propose to review the purpose of the information sheet for paediatric CC.

Concept in terms of medical ethics: notion of autonomy

Autonomy from the Greek autos ‘one’s self’ and nomos ‘rule’ designates the power of persons to make decisions that concern themselves. To be autonomous, a person must be able to evaluate his/her options rationally, according to the facts and taking account of the consequences [6—8].

Since the 1970s, the relationship between doctors and their patients has evolved considerably. The concept of autonomy of the patient has substantially changed the practice of medicine and the paternalistic notion that ‘the doctor is always right’ has fallen by the wayside. In the past, the doctor ‘spared’ the patient the responsibility of decision. Today, doctors must provide patients with information. They must help them to make informed choices. They must abide by their choice to refuse treatment. They must withhold nothing from their patients. Doctors cannot impose their desires and preferences on those of the competent patient. Currently, patients are considered Persons, with, as the corollary, the emergence of patients’ rights [9,10]. Patients have become ‘actors’ with regard to their health, free to decide for themselves.

Modern healthcare ethics is based on the following concepts: benevolence, autonomy, absence of malice, equity and responsibility. The health authorities (Haute Autorité de santé [HAS]) and healthcare policy emphasize the absence of malice or rather ‘good treatment’ as the appropriate healthcare attitude, which should be professional, active and dynamic, individual and collective and have its roots in human values. It is based on ‘good manners’ [11].

The European concept of autonomy is accompanied by notions of vulnerability, dignity and integrity. This is an essential notion in that it makes the person a moral actor. Consent is the unequivocal condition in the principle of autonomy. Consent must be obtained only after the information has been given to and received by the patient. This assumes that the patient must be able to understand and assimilate the information [7,12,13].

Technical advances in the world of medicine and the apprehension of society as a right make it more and more difficult to apply the concept of autonomy strictly.
Purpose of information sheets

The need to inform patients using validated scientific data is acknowledged internationally. The Council of Europe acknowledges ‘the right of patients and citizens to be provided with and to have easy access to relevant information about their health and healthcare in a format and language they can understand’. This information should be based on scientific data derived from practice guidelines and be made available in formats suited to several target audiences (healthcare professionals, patients and decision-makers) [12–14].

Particularities of French legislation

The obligation to inform patients is based on a fundamental principle of French law: the principle of the inviolability and inalienability of the human body.

This principle is defined in article 16-3 of the Civil Code, which stipulates that ‘the integrity of the human body cannot be interfered with except for the medical needs of that person or exceptionally in the therapeutic interest of others. The consent of the person concerned must be collected beforehand, unless the state of the person makes it impossible for him/her to provide consent for the necessary therapeutic intervention’ [15].

To obtain this required consent and before the care is provided, the patient (or their legal representative for minors) must have received clear, accurate and understandable information [9,10].

Article 3 of the Charter for Hospitalized Persons states that the information given must be ‘understandable and accurate’. Hospitalized persons take part in the therapeutic choices that concern them. They can be assisted by a person of trust whom they can choose freely. A medical act can only be performed once the patient has freely provided informed consent. The patient has the right to refuse any treatment [16].

The law relative to patients’ rights and the quality of the healthcare system, enacted on 4th March 2002 [17], made it possible to incorporate into the Public Health Code the procedures to follow with regard to information and patients’ consent. The principles are based on the Hedreul jurisprudence resulting from a Supreme Court decision dated 25 February 1997 [18].

In accordance with the law of 4th March 2002, the healthcare professional is obliged to provide information about all of the risks unless they are benign or rare. This information can be provided orally unless the law states otherwise. Written consent is necessary in the following situations:

- medical assistance for procreation;
- donation and utilization of elements and products of the human body;
- the taking of organs for transplants;
- samples taken for scientific purposes;
- voluntary termination of pregnancy;
- genetic examinations;
- fallopian-tube sterilization;
- biomedical screening; and research [17].

Paediatric cardiac catheterization: an information sheet

It is not compulsory to obtain written consent before medical acts such as paediatric CC, but as it is a procedure performed on a minor, it is recommended to have both parents sign a document authorizing the treatment in order to ensure traceability. Consent must be obtained only after clear understandable information has been provided verbally or in writing by the practitioner during a specific interview [9,10,15].

The laws and recommendations have encouraged the development of good practices. Through a series of questions, we propose to help practitioners respond appropriately in certain situations of conflict or in medical emergencies.

In paediatric cardiac catheterization, to whom must the information be given and who must provide the consent?

Whatever the minor’s family situation, both parents must be consulted, in principle, if they are joint holders of parental authority. Unless otherwise decided by a judge, divorced or separated parents jointly exercise parental authority.

The person the information is given to is the patient, who may be a minor or an adult under guardianship, in which case the information must be adapted to their level of maturity and their faculties of discernment. Holders of parental authority will also be informed unless the minor objects.

Article L1111-2 of the Public Health Code (PHC) states that: ‘This information concerns the different investigations, treatments or preventive actions that are proposed, their usefulness, the immediate need if necessary, their consequences, the foreseeable frequent or serious risks they carry and other possible solutions and the foreseeable consequences in case of refusal. When, in the wake of investigations, treatments or preventive actions, new risks are identified, the person concerned must be informed about them, unless the person cannot be traced’ [19].

Article L1111-2 of the PHC states that: ‘Every person has the right to be informed about his/her state of health. It is incumbent on every healthcare professional to provide this information in accordance with his/her expertise and in the respect of professional rules that apply to him/her. Only emergencies or the impossibility to inform the patient release the professional from this obligation. This information is delivered during an individual interview. The wish of persons not to be informed about a diagnosis or prognosis must be respected, unless third parties may be exposed to a risk of transmission. The rights of minors or adults under guardianship mentioned in the present article are exercised, depending on the case, by those with parental authority or by the legal guardian. These will receive the information provided for in the present article, subject to the provisions set out in article L1111-5. The parties concerned have the right to receive the information themselves and to take part in making decisions that concern them, in a manner
that for minors is in keeping with their level of maturity, and for adults under guardianship, that is in keeping with their faculties of discernment’ [17,19,20].

What is the procedure if the holders of parental authority are separated or divorced?

Article R4127-42 of the French PHC stipulates that 'divorced or separated parents jointly exercise parental authority, unless the judge has decided otherwise. Divorced or separated parents therefore exercise parental authority jointly and must both be informed and consulted for major decisions concerning their child’ [21].

Article 372-2 of the French Civil Code specifies that ‘in the view of a third party acting in good faith, each of the parents is considered to act with the agreement of the other, when he/she alone effects a usual act of parental authority for the child’ [22].

CC cannot be considered a usual act in the eyes of the law.

How must the information on cardiac catheterization be communicated?

Verbal information is essential and must be adapted to each individual. It is necessary to spend time to be patient, to listen carefully and, if needs be, to modulate the information depending on the situation of the child and their family. A document or comprehensive information sheet is a complement to the verbal information given by the healthcare professional but in no way replaces it. The sole aim is to give written information to the child and the parents so that they can think about the situation after the interview; it is not necessarily given for the parents or their representatives to sign. There must be no statement obliging the patient to sign.

It is recommended to provide objective information without dramatizing the situation or expressing undue optimism according to the following principles:
• give quantitative information about the frequency of the disease or its symptoms;
• describe the benefits/risks and the consequences of treatments on the patient’s everyday life;
• propose a list of questions that the patient can ask a healthcare professional;
• indicate sources of complementary information;
• clearly mention the authors of the information, the different fields they work in, the sources of information and any funding, as well as the date the document was drawn up.

Generally, this information is given at the time of the interview with the parents and the infant. Written consent is not compulsory. In the majority of cases the information covers the following points:
• the indication;
• the procedure itself;
• the objectives;
• the risks;
• possible complications.

As often as possible, if the child’s state of health allows, the parents and the child if they are old enough to understand must be given a period of reflection between the time the information is provided and the procedure itself [23].

How are the information sheets and consent forms drawn up?

Guidelines for good practices on the delivery of information have been established by the HAS and officially recognized in a decree from the Ministry of Health. These documents allow professionals to draft a written information document for patients and healthcare users. This document completes the information provided orally by the healthcare professional, but in no way replaces it. This document must help the patient to take part in decisions that concern their health. These guidelines are available on the Internet site of the HAS. Advice based on published studies and patients’ preferences concerning the presentation of these written documents and about writing them is also available [23] (Table 1).

The French Society of Cardiology has proposed an example of a written consent form for CC [24]. It is up to every professional to tailor their own information sheet, alternating text, scientific references and diagrams to explain as clearly as possible to the parents and to children old enough to understand the indication for the examination, the objectives, the risks and the complications of CC, whether for diagnostic or interventional purposes.

Concerning the information, it is always useful to refer to the recommendations of the French Code of Medical Ethics, which stipulates in article 35 that ‘the doctor must provide to persons […] being treated […] accurate, clear and understandable information on their state, and the investigations and care proposed. […] the doctor takes into account the personality of the patient when giving these explanations and makes sure they are understood’ [10].

Can emergency cardiac catheterization be performed if the parents are not available to receive the information and give their consent or if they oppose the procedure?

When the parents are absent and cannot be contacted by modern means of communication (mobile phone, fax, message recorded by the emergency services, etc.) and if the situation is serious and an emergency, the practitioner must take the necessary steps to provide the care under his/her personal responsibility. This is the sense of article L1111-5 of the French Public Health Code, which stipulates that the ‘doctor called upon to provide care to minors […] must make every effort to contact the parents or the child’s legal representative and obtain their consent. In cases of emergency, and if the guardians cannot be contacted, the doctor must provide the necessary care’ [25,26].
Table 1  Patients’ and users’ preferences with regard to brochure presentation: Haute Autorité de santé/Guidelines Department/June 2008.

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive, reassuring, encouraging, optimistic, constructive tone/mood</td>
<td>Negative, alarmist tone, focusing too much on what is wrong</td>
</tr>
<tr>
<td>Honest, practical, understanding, not condescending tone/stance</td>
<td>Unrealistic, glosses over real problems and possible after effects, overoptimistic, childish</td>
</tr>
<tr>
<td>Personalized tone: talks to 'you', treats you as an individual, warm, warmly, human touch</td>
<td>Impersonal tone: talking about patients in general, impersonal, cold, distant, too formal</td>
</tr>
<tr>
<td>Clear vocabulary, easy to read and understand, plain speaking, simple</td>
<td>Complicated language and explanation, too technical, badly written</td>
</tr>
<tr>
<td>Short sentences, explanation of terms</td>
<td>Dense text, too long, lacking any structure</td>
</tr>
<tr>
<td>Structured and concise text, clear headings, important sections highlighted, short block of text</td>
<td>Small print, hard to read, unattractive layout, boring presentation</td>
</tr>
<tr>
<td>Legible font size</td>
<td>Amateurish, looks 'cheap', appearance of cost-cutting</td>
</tr>
<tr>
<td>Professional-looking production</td>
<td>Balanced mix of text and illustrations</td>
</tr>
<tr>
<td>King’s Fund focus group discussions [23].</td>
<td></td>
</tr>
</tbody>
</table>

This does not release the doctor from the obligation to inform minors according to their level of maturity and to seek their consent if they are able to express their wishes and contribute to the decision; this is particularly the case for teenagers [19].

If the parents refuse the procedure proposed and the procedure is not urgent, it is useful to provide the information and give the parents time to think carefully about the situation and the information provided before they make their final decision.

In contrast, if the parents refuse the medical procedure, which needs to be performed quickly, the doctor cannot accept a single refusal. In such cases, the doctor must make every effort to convince the parents by providing once again all the necessary information and details and by making sure that they have been correctly understood. The doctor must propose seeking the opinion of a colleague.

If the parents reiterate their refusal, the doctor can only act if the minor’s health or life is in danger. In such cases, the Public Prosecutor must be informed and minor must be given the necessary care [9].

What can be done if the minors explicitly oppose the presence of the holder(s) of parental authority at the consultation so as to keep the state of health secret?

The law of 4th March 2002 provides for the derogation of parental authority as defined in article 371-2 of the Civil Code. By this means, the doctor can proceed without the consent of the holders of parental authority when minors explicitly ask the doctor to keep their state of health secret from their parents and when the treatment or procedure is necessary for their health. These two conditions are cumulative and the derogation provided for by the law must remain an exception to the principle of obtaining the consent of the parents [17,18,20,25].

This right of minors to secrecy also applies to the consultation of their medical record by their parents. Minors can oppose giving their parents access to their medical records [17].

This new provision falls within the recognition of the legal independence and the specific rights of children, declared in 1990 by the Convention for the Rights of the Child. Article 12 states that children are capable of discernment, that they have the right to express their opinions freely on any matters that concern them and that their opinion must be taken into account depending on their age and their level of maturity [27].

This possibility provided for by the law puts the doctor in a ‘rather uncomfortable’ situation. It is for this reason that the doctor must always make every effort to obtain the consent of the minor during a consultation attended by the holders of parental authority; in cases of reiterated refusal by the parents, the minor must, during medical consultations and procedures, be accompanied by an adult of their choice.

Here, the responsibility of the practitioner consists in providing full information to the minor on the gravity of the decision to exclude the holders of parental authority and in ascertaining the identity and quality of the adult chosen to accompany the minor [20,25].

In the case of CC, it is difficult to imagine not involving the parents in the consultation and not obtaining their consent for the procedure. These provisions, which can be applied in principle, do not seem to be realistic in the present case.

What can be done if the parents refuse to read or to listen to the information concerning the risks of catheterization?

If one or both parents do not wish to know the modalities and the risks of a diagnostic or therapeutic procedure such
as CC, the derogation set out in the Code of Medical Ethics cannot be applied. Indeed, signed consent is not valid if no precise detailed verbal information was given beforehand. In any case, this must be reported in the child’s medical record.

In cases other than a medical emergency, the examination must, if possible, be postponed until the information can be provided and signed consent can be obtained from the parents and the child who is old enough to understand.

The healthcare professional can seek assistance from the legal expert of the establishment.

Is it necessary to list all of the risks of paediatric cardiac catheterization and the potential complications, with the risk that parents may refuse the procedure?

The doctor/patient relationship is based on confidence. Withholding information, notably on the risks of paediatric CC, would jeopardize this relationship and may lead to legal repercussions. Information on the indication, the modalities of the examination and its risks is provided during the successive consultations and ideally during specific interviews with the child and the parents. In our society, which values fast action and results, it is necessary to give the parents and child time to think about the information provided. This, of course, is not possible in emergency situations. The hospital practitioner must adapt his explanations to the different situations.

What are the legal implications?

The traceability of information given to the patient or his/her legal representative, the content of the patient’s medical record and recording the consent for care are major legal issues.

Indeed, in the absence of medical malpractice or technical errors in carrying out a medical act, which nonetheless led to a prejudice for the patient (therapeutic misadventure), patients and their legal advisors may seek possible shortcomings in the delivery of information: ‘If I had been informed of the risks associated with this procedure, I would never have accepted it’.

In cases when a fault-free prejudice related to a medical act occurs, compensation for the victim is the responsibility of the Office National d’Indemnisations des Accidents Médicaux. In contrast, if there was a shortcoming concerning the information, compensation is paid in part by the healthcare establishment or by its insurer, as an error with regard to the information is considered a fault.

The law of 4th March 2002 regarding the rights of patients and the quality of the healthcare system states that ‘In cases of litigation, it is the responsibility of the professional or the healthcare establishment to provide proof that the information was given to the person concerned in the conditions set out in the present article. This proof can be brought by any means’ [17,18].

What about information to be given after the prejudice?

The declaration of a healthcare-related prejudice is not only a moral and ethical duty, but also a legal obligation. According to Article L1142-4, ‘Any person who is a victim or considers themselves a victim of a prejudice related to an act of prevention, diagnosis or healthcare or their beneficiaries, if the person died, or, if necessary, the person’s legal representative, must be informed by the professional, the healthcare establishment, the healthcare services or the organization involved in the circumstances and the causes of this prejudice. This information must be provided within 2 weeks at the latest following the discovery of the prejudice or at the explicit request of the person, during an interview during which the person can be assisted by a doctor or another person of their choice’ [28].

Patients have a fundamental right to be informed following any prejudice.

In addition, the V2010 certification procedure for healthcare establishments, based on legal texts, stipulates that ‘information to the patient in cases of a prejudice related to healthcare’ is a requirement in the care of patients (Criterion 11.c) [29].

Any ‘adverse event’ that leads to a physical or psychological prejudice must be declared, whether it is subsequent to the complications related to the patient’s disease, to a therapeutic accident or to an error.

The gravity of the prejudice will be assessed from the patient’s point of view and not that of the healthcare provider, who may tend to minimize the repercussions.

In order to help healthcare professionals in this difficult and often distressing situation for the teams and families, in March 2011 the HAS issued a guide for healthcare professionals working in healthcare establishments or in other types of practice. The guide is entitled ‘Improvement in practices and the safety of patients: declaration of a healthcare-related prejudice’ [30].

We found no jurisprudence concerning inadequate information before paediatric CC.

What are the possible risks and complications in paediatric cardiac catheterization?

In any case requiring paediatric CC, whether there is an interventional act or not, the doctor is obliged to give a maximum amount of information.

Adverse events can occur throughout the CC procedure, from premedication for sedation, vessel puncture and diagnostic CC to therapeutic interventions. The following are the most common complications: exposure to ionizing radiation (decreasing with newer equipment); risk of general anaesthesia (when used); hypothermia (especially in small patients); aggravation of hypoxaemia; arrhythmia (temporary or even permanent instability, as in heart block); vascular injury, perforation or tears. Other complications include cardiac perforation, cardiac valve injury, blood loss that requires transfusions, thromboembolism, allergic reaction (to contrast agents, drugs or anaesthetics), renal
insufficient (caused by contrast agents), diffuse central nervous system injury, stroke and death [31].

According to recent studies, diagnostic CC and interventional procedures are associated with a low risk of severe complications (1.91–9.3%) and a low mortality rate (0.14–0.2%) [32–37]. In recent years, paediatric CC has continued to be associated with complications, although the overall incidence appears to be decreasing. Independent risk factors for a complication include young age (<6 months), male sex, inpatient status and the year of catheterization [36,37].

More complex complications for each interventional procedure are summarized in the literature [3–5,31,38,39].

Is it necessary to inform parents and the child about the risks of ionizing radiation during paediatric cardiac catheterization?

CC is one of the radiological X-ray procedures with the highest doses of radiation. This is of great concern in a paediatric setting because of the higher tissue sensitivity in infants and children. Infants and children are at least three times more sensitive than adults to radiation-induced malignancies [40].

Over the last few years, an increasing number of therapeutic catheterization procedures have been performed in children. Interventional cardiology procedures are known to give high-doses of radiation to patients because of prolonged fluoroscopy, multiple cine runs and the complexity of the procedures. Moreover, in children with congenital heart disease, there is often a need to perform multiple examinations, thus increasing the radiation damage [41,42].


Article 9 of that directive expressly requires special attention to be paid to the radiological exposure of children and interventional radiology. There are few studies on the exposure of children to radiation during CC and its dependency on growth.

Because of the moderate values of doses in paediatric CC, radiation-induced skin injuries are unlikely. To assess the potential risk of stochastic effects such as cancer and leukaemia resulting from CC procedures, the effective dose should be calculated. However, to assess the potential risk of stochastic effects resulting from CC procedures, the effective dose can be calculated with the multiplicative model recommended in the International Commission on Radiological Protection Publication 60, which used age and sex-dependent risk factors (13%/Sv for boys and 16%/Sv for girls aged 10 years) [44] (this refers to Publication 103).

Determining the effective dose in CC procedures is not straightforward because of the complexity of the X-ray beam geometry and field size variations during examinations. Moreover, individual anatomy should be taken into account. Anatomy is very important for dose estimations in children because patients' weights and heights may vary considerably. Using only the standard paediatric mathematical phantoms of 0, 1, 5, 10 and 15 years could result in errors as large as 25% [40].

The overall correlation between radiation risk and patient's age was poor. However, a much higher median risk estimate was found, as there was a significant increase in effective dose with decreasing age [41,42].

Risk estimates for late effects in these patients have been based on the linear extrapolation of high-dose data as obtained in the lifespan study of atomic bomb survivors: the linear-no-threshold model. The concept ignores any self-healing process by the cell and the affected organism. These assumptions are increasingly called into question in the literature.

Various studies in the literature suggest, via the use of a biomarker (from circulating lymphocytes), that low doses of radiation have a deleterious effect on deoxyribonucleic acid (DNA). Studies of these biomarkers seem to show long-lasting effects of chromosomal damage in children with congenital heart disease [45]. The use of γ-H2AX foci as a biomarker of DNA damage suggests that the risk of cancer calculated according to the linear-no-threshold model is possibly underestimated [46] (Table 2).

Leukaemia and cerebral tumours are rare cancers with a low cumulative absolute risk. Recently, Pearce et al. showed that for a cumulative delivered dose of 50–60 mGy during tomodensitometry in a cohort of children and young adults, the risk of leukaemia and cerebral tumours was multiplied by three [47].

What is known about the risk of stochastic effects during paediatric cardiac catheterization?

To answer this question a national multicentre study is currently being finalized under the auspices of the Institut National de Radioprotection et de Sûreté Nucléaire.

Despite its limits, the linear-no-threshold model has a useful regulatory role because it can be applied to form a simple and effective framework for radioprotection (as low as reasonably achievable [ALARA] principle) [48].

The goal of the ALARA concept as applied to CC is to provide maximal diagnostic and therapeutic benefits while exposing patients to the lowest possible dose of radiation. Techniques and strategies to manage radiation doses are detailed in the literature and enable the paediatric cardiologist to produce high-quality images at low radiation cost to the patient [46].

Data in the literature emphasize that when managing a serious condition, such as complex congenital heart disease, we also have to protect patients from risks that may become clinically manifest after years and even decades. We should justify the indication and optimize dose delivery by adjusting doses, reducing multiple scans and contrast agents and eliminating inappropriate referrals. Recently, a paper reviewed how physicians could meet the ideals of informed consent with regard to cardiac imaging with ionizing radiation, given the limited evidence of risks and benefits. The goal is to have an informed patient making rational choices based on available medical information [49].

These practices have been recommended internationally. In Europe, the principles of justification, optimization and responsibility are also reinforced by the Erratum law [43].
Table 2  Potential clinical effects of radiation exposure [49].

<table>
<thead>
<tr>
<th>Threshold dose (Gy)</th>
<th>Time of onset</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin effects</td>
<td></td>
</tr>
<tr>
<td>Early transient erythema</td>
<td>2</td>
</tr>
<tr>
<td>Mean erythema reaction</td>
<td>6</td>
</tr>
<tr>
<td>Temporary depilation</td>
<td>3</td>
</tr>
<tr>
<td>Permanent depilation</td>
<td>7</td>
</tr>
<tr>
<td>Dermal necrosis</td>
<td>&gt; 12</td>
</tr>
<tr>
<td>Eye effects</td>
<td></td>
</tr>
<tr>
<td>Lens opacity</td>
<td>&gt; 1–2</td>
</tr>
<tr>
<td>Cataract</td>
<td>&gt; 5</td>
</tr>
</tbody>
</table>

Gy: gray.

In France, these principles were included in the CSP in 2002 [50].

**Conclusion**

Before implementing diagnostic or therapeutic strategies, such as paediatric CC, the healthcare professional must explain the disease, the advantages and drawbacks of each treatment strategy and their foreseeable benefit/risk ratio in order to help children and their parents to come to a decision. An information sheet cannot replace verbal information. This information should be based on scientific data derived from practice guidelines and be made available in formats suited to several target audiences. In the event of complications, the healthcare provider must prove that the information was provided and explained.

Practice patterns such as justification, optimization and responsibility have been recommended and were included in the PHC in 2002.

Ten years after the law of 4th March 2002, developments concerning information are expected. These will probably reinforce both the autonomy of patients in their choices and the obligation of the healthcare provider to provide the information necessary to obtain informed consent.

**Disclosure of interest**

The authors declare that they have no conflicts of interest concerning this article.

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[14] Chartre européenne des droits du patients (Article 35 de la Charte des Droits Fondamentaux de l’Union Européenne, Rome,


