

# Producing effective treatment, enhancing safety: Medical physicists' strategies to ensure quality in radiotherapy

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## ▶ To cite this version:

Adelaide Nascimento, Pierre Falzon. Producing effective treatment, enhancing safety: Medical physicists' strategies to ensure quality in radiotherapy. Applied Ergonomics, 2011, vol. 43 (n° 4), pp. 777-784. 10.1016/j.apergo.2011.11.011. halshs-00870718

# HAL Id: halshs-00870718 https://shs.hal.science/halshs-00870718

Submitted on 7 Oct 2013

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1	Producing effective treatment, enhancing safety:
2	medical physicists' strategies to ensure quality in radiotherapy
3	
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11	
12	Abstract
13	The purpose of this article is to understand the way in which medical physicists take into
14	account treatment effectiveness and safety when selecting a treatment plan, with respect to the
15	medical prescription and the technical, human and organizational resources available. Data-
16	gathering was based on the allo-confrontation method: 14 medical physicists from five
17	different treatment centers commented on real treatment plans that had been drawn up by their
18	colleagues. Results show that medical physicists have two means at their disposal to control
19	treatment effectiveness and safety: risk avoidance and risk reduction. Risk avoidance is
20	achieved when conceiving the solution. Risk reduction occurs after the design of the plan and
21	consists in accompanying and assisting the radiographers at the work station where the
22	treatment is carried out.
23	

Key-words: safety, effectiveness, quality, radiotherapy 

#### 27 **1.** Introduction

The US Institute of Medicine reports « Crossing the Quality Chasm » (2001) describes the 6 following dimensions of quality in health care: (1) Safety, (2) Effectiveness, (3) Patient centeredness, (4) Timeliness, (5) Efficiency and (6) Equity (Berwick, 2002). This research has considered dimensions 1 and 2, treatment safety and effectiveness. The goal is to investigate physicists' strategies when a possible conflict between these two dimensions arrives. In this text, « quality » refers to the respect of these two dimensions in radiotherapy treatment.

35

#### 36 1.1 Quality in radiotherapy : effective treatment and patient safety

37

Every year in France, about 180 000 patients suffering from cancer pathologies are treated by 38 39 radiotherapy. Radiotherapy is a medical technique that consists of irradiating a tumor by 40 means of a beam of ionizing irradiation. The objective of radiotherapy is to reduce the volume 41 of the tumor by optimizing the concentration of the prescribed dose within the tumor itself 42 and minimize irradiation of surrounding healthy tissues (Le Bourgeois, 2006). In practice, 43 this is carried out through sessions in which fractions of the total dose are administered using 44 various techniques which determine the shape of the radiation beams and the parameters of 45 the machines used in the treatment.

The advantages of this treatment modality include a good effectiveness (40% of cured patients have had a radiotherapy), the conservatory aspect of the treatment (no surgery), and a good cost/effectiveness ratio (in France, cancer treatments cost 12 billions euros per year, including 0,9 billions of euros for radiotherapy) (Le Bourgeois, 2006).

50 Although radiotherapy contributes in a large way to the cure of cancer, it nevertheless presents

risks that can have important consequences for the patient's health, as recent accidents that have occurred round the globe have shown (CIPR, 2003; Cook, Nemeth, & Dekker, 2008; Nascimento, 2009; SFRO, 2008). Exposure in radiotherapy is considered to be accidental if there is a wide discrepancy between the prescribed parameters for radiation and the actual treatment (dose/volume) administered to the patient. The difference can be due to overdosage (the dose administered is higher than the one prescribed) or underdosage (the dose administered is lower than the one prescribed): both must be avoided (CIPR, 2003).

Patient safety in radiotherapy has become a public issue in France following the radiotherapy accident which occurred in Epinal in 2005. The investigation report states that, between 1989 and 2005, 4 900 patients experienced an overdosage of 7% caused by a calculation error. This accident is considered to have affected more patients than any other (Peiffert, Simon, & Eschwege, 2007).

63 The publicity given to this accident has led to increased quality requirements in radiotherapy:64 on top of clinical effectiveness, radiotherapy has to be safe.

65

#### 66 1.2 Radiotherapy care providers : the role of medical physicists

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In France, the preparation of treatment plans in radiotherapy requires four types of professionals: radiation oncologists, medical physicists, dosimetrists and radiographers. The radiation oncologist is responsible for prescribing the treatment (method and total amount of radiation). Radiographers simulate patient positioning and fashion immobilization devices at the simulation work station. Following this phase, a medical physicist and a dosimetrist work together to design the treatment plan (beam distribution, dose fractionation). This plan is assessed by the radiation oncologist. On the basis of this plan, radiographers define the real conditions for positioning the patient. These last modifications are then checked by a medical
physicist. Finally, radiographers administer the actual treatment.

77 It should be noted that the physicists contribute to the radiotherapy treatment chain at a point 78 situated between the physician's prescription for treatment and the administration of the 79 treatment by the radiographers. On the one hand, they must design a treatment plan that 80 conforms to the constraints determined by medical protocol and/or the physician in charge of 81 the patient. This phase is carried out virtually: using dedicated software, the physicist tests 82 various combinations of beams (angular position, intensity, use of filtering devices, etc.), and checks the resulting distribution of the dose. This "virtual phase" results in a "treatment 83 84 plan"<sup>1</sup>, which, after validation by the physician, will be implemented by the radiographers. On 85 the other hand, they must make sure that the treatment plan actually can be carried out in real 86 situations – according to the material and human resources that are available – and in safe 87 conditions, i.e., conditions that allow the radiographers to control the risks involved in 88 administering the treatment. The physicists' objectives are thus to guarantee the effectiveness 89 of the treatment (and therefore the health of the patient), by means of a treatment plan which complies with the medical prescription, and to ensure patient safety by minimizing the risks, 90 91 if any, in implementing this plan.

Even though scientific and technological progress has contributed to improving healthcare in terms of clinical effectiveness, the gains for patient health are accompanied by the presence of new risks for patient safety (ANAES, 2003; Carayon, et al., 2006). Indeed, medical physicists have access to highly effective techniques, which meet the requirements of the medical prescription, but which present certain risks, especially regarding the difficulties the radiographers encounter in executing the treatment. These situations may lead to conflicts

<sup>&</sup>lt;sup>1</sup> A treatment plan determining the quantity and the placement of the radiation beams, the distribution of the beam dose, the positioning of the patient and the accessories to be used.

98 between treatment effectiveness and safety. In some cases a treatment may be very effective 99 from a clinical point of view, but very risky to carry out. If the risks of implementation are 100 reduced, the opposite situation may arise: the treatment will carry fewer risks, but will also be 101 less effective at the clinical level. At some point a decision must be taken to reach the best 102 compromise between effectiveness and safety.

The conflict between effectiveness and safety is not particular to radiotherapy. Various authors have identified such a conflict and described the way in which it is managed in other situations (Caroly & Weill-Fassina, 2004; Gomes, Woods, Carvalho, Huber, & Borges, 2009; Toupin, 2008). The goal of this study is to understand the way in which medical physicists take into account treatment effectiveness and safety when selecting a treatment plan, with respect to the medical prescription and to the available technical, human and organizational resources.

110

#### 111 **2. Method**

112

113 The data-collecting method that was used at this stage consisted of presenting real treatment 114 plans to medical physicists using an interview method known as "allo-confrontation". Allo-115 confrontation involves asking the subjects to comment on traces of their colleagues' activities. 116 (Mollo & Falzon, 2004). Such traces can be a video-recording, a plan produced as a solution 117 to a problem, a transcript of a dialogue, etc. In this case the traces were the treatment plans 118 which were provided in paper format. This method is applicable to this study: confronting 119 subjects with an activity they practice but which is performed by someone else, without the 120 latter being present, allows participants to explain their representations about real cases. 121 Additionally, this method help subjects to develop their knowledge by getting aware of other 122 types of representations (Mollo & Falzon, 2004).

123	
124	2.1 Sample
125	
126	We contacted 40 medical physicists attached to radiotherapy centers in the Paris area. For
127	comparative purposes, we chose subjects in centers of differing legal status (Centre de Lutte
128	Contre le Cancer - CLCC, public and private establishments) and differing resources (cutting
129	edge or conventional). Table 1 presents the 5 establishments were the study was conducted. It
130	is to be noted that:
121	the two CLCCs are major French research and treatment conters, which persons
151	- the two CLCCs are major French research and treatment centers, which possess
132	top-level equipment and a large staff; all observed centers have a record and verify
133	system.
134	- the three other establishments are smaller-scale hospitals, located in Paris or its
135	vicinity, with good but less diverse equipment and a smaller staff. However, they
136	should not at all be considered as second-class establishments.
137	The reason for choosing these two categories of establishments is not based on an
138	hypothetical difference in safety or effectiveness, but on the hypothesis that optimal solutions
139	(i.e. safe and effective decisions) are resource-dependent. Resources may be human, technical,
140	organizational.
141	In all, 14 subjects, (7 women + 7 men) from five different centers participated in the study.
142	The subjects had between two and thirty years of experience in the profession. The
143	distribution of the subjects according to the centers is presented in Table 1. Each subject dealt
144	with the two treatment plans, in the same order.

Center	Status	Number of accelerators	Available means	Medical physicists
A	Specialized Cancer Center (CLCC)	7	Classic Conformational IMRT <sup>2</sup> Tomotherapy	5
В	Private establishment	3	Classic	2
С	CLCC	6	Classic Conformational IMRT	2
D	Public establishment	3	Classic Conformational	2
E	Public establishment	2	Classic Conformational	3
	·	Total		14

145 **Table 1 : Study sample** 

146

147 **2.2** *Procedure* 

148

149 2.2.1 Selection of treatment plans

150 The selection of the treatment plans was made possible with the help of a medical physicist

151 from the A sample. The following were chosen:

152 - one case classified as simple, following a protocol : the medical prescription was

 $<sup>^2</sup>$  The technique known as IMRT (Intensity Modulated Radiotherapy Treatment) delivers a standard dose, but also allows for a variation in the intensity of the dose emitted inside each beam. It is thus possible to increase the total prescribed dose, as it will be more concentrated in the target volume, compared with a classic or conformational technique.

respected and optimized, and the implementation did not present any particular risks ; This case concerns a treatment plan for a prostate tumor. The total dose prescribed is 80 Gray distributed in 40 fractions (2 Gray per session, five coplanar beams).

156 one case classified as complex, not following a protocol: in order to find an optimal 157 solution for the medical prescription, certain decisions were made. However, this treatment 158 solution, very effective in its virtual version, might create difficulties for the actual 159 implementation of the treatment. The deliverance of the dose may be quite long: this can lead 160 to undesirable movements of the patient on the table (which are a risk for both effectiveness 161 and safety) or to delays at the workstation (which are a source of planning disorganization and 162 stress to radiographers, and ultimately a risk for both effectiveness and safety); these 163 difficulties could be taken into account at another stage. This case concerns a treatment plan 164 for a brain tumor. The treatment is delivered in two sessions: at first the dose prescribed is 24 165 Gray distributed in 15 fractions (1.6 Gray/session, five non-coplanar beams), then the dose 166 prescribed is 16 Gray distributed in 10 fractions (1.6 Gray/session, six non-coplanar beams).

#### 167 2.2.2 Validation phase

The experimental procedure was validated with the collaboration of a second medical physicist on site A (not the same one who helped us to select the two treatment plans). The validation phase involved presenting the two treatment plans to this second physicist under the same conditions as those were be used for the actual experiment. This allowed us to estimate the physicist's comprehension of the treatment plans presented and to evaluate the time needed for allo-confrontation interviews.

#### 174 2.2.3 Follow-up allo-confrontation interviews

175 The interview instruction was presented orally to the physicists individually. The first part of 176 the instruction was a review of the research project and its objectives. The instruction itself 177 required the subjects to comment on the two treatment plans. Instructions were as follows:

"I am going to show you two treatment plans drawn up by other professionals. I would like
you to comment on the choices made by these professionals. What interests us is the logic
behind these proposals. In dosimetry it is normal to have several different possible solutions.
The issue is not to evaluate their quality. I would just like you to comment on the choices
made by your colleagues and to tell me how they resemble or differ from what you would do
yourself and why you choose to do what you do. I will present one case to you, then the other.
You can ask questions at any time."

The individual interviews lasted about 30 minutes and were conducted by the first author on the physicists' workstation. The data were collected between March and May, 2009. The interviews were recorded, and then transcribed in full.

188

#### 189 2.3 Data analysis

The transcription of the 14 interviews concerning the two proposed plans provided 28 verbal
transcripts (14 subjects x 2 treatment plans). A content analysis was performed manually.

192 Coding categories have been defined in relation to research needs. Five categories have been 193 set: i) criteria used to evaluate solutions ; ii) assessment of solution acceptability ; iii) criteria 194 of acceptability ; iv) proposed solutions; v) strategies aiming at reducing risks in 195 implementing the solution.

196 This paper considers the results regarding the first and the last criteria. Criteria used to 197 evaluate solutions concern factors like the number of beams, their relative intensity, the 198 distribution of the dose within the volume to be irradiated, the type of contention devices the 199 duration of the irradiation, the type of equipment, etc. Strategies aiming at reducing 200 difficulties in executing a solution may concern either ways to avoid risks (taking in account 201 technical, human or organizational factors as well as patient comfort) or ways to assist 202 radiographers (oral and written communication, actual presence in the irradiation 203 workstation).

The data were analyzed qualitatively by coding the interview, and quantitatively by the frequency of appearance in a given category.

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207 3. Results
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In brief, results show that physicists tend to give prominence to the treatment effectiveness in the virtual phase and to consider safety next. But they also show that physicists use prevention strategies in order to avoid execution errors, in particular by taking into account difficulties radiographers may meet.

## 213 3.1 Searching for a solution : effectiveness and safety criteria

When analyzing the treatment plans, medical physicists indicated the criteria they used in order to design or evaluate a plan of treatment. Two criteria were identified: the effectiveness of the treatment and the safety of the treatment.

217 *3.1.1 Effectiveness* 

For the subjects, the "effectiveness" of the treatment means the attainment of optimal dosimetrics, in other words, the maximum success of the treatment from a clinical standpoint. A treatment is effective when the best distribution of the dose has been attained i.e., at least 95% of the prescribed dose is delivered within the target volume and a minimum amount is delivered in surrounding organs, known as "organs at risk". The effective solution is thus the one that allows for better control of the tumor with minimum damage to the organs at risk. A
first type of trade-off is made at this level. This trade-off takes into account several facts:

the locally available machines. A solution may be judged theoretically ideal but
practically inapplicable due to the absence of a specific technology in the physicist's facility.

the technical limitations of the available machines. In all, 10 subjects expressed the
idea that some solutions that are appealing during the design of the treatment plan (i.e. during
the virtual phase) may not be feasible in reality, due to some physical characteristics of the
machine. The solution originally planned, considered to be most effective, has to be adapted
so that it can actually be carried out.

We have not got any x-ray transparent tables. We have a table and two iron bars. Everything that is done from behind, for example, hits against the iron bar, and so, in reality, we can't actually do it. **P13, Center C** 

235

Effectiveness is a shared criterion: all of the 14 subjects mentioned the need to fulfill thisobjective when designing or evaluating a treatment plan.

238	I look at the dosimetric solution because my priority is for the patient to receive good treatment.
239	That means the prescribed dose for the tumor – and I look at the organs at risk and the healthy
240	tissue as well. P1, Center A
241	We are scientists, we look at the distribution of the dose, and we always try to find the ideal
242	solution. P12, Center B
0.42	

243

244 *3.1.2 Safety* 

The safety criterion is associated with the implementation risks that a treatment plan may entail. The physicists must make sure that the effective dosimetric solution, as programmed virtually, can be carried out in safe conditions, i.e. in conditions that allow radiographers to safely perform the treatment. A safe treatment is a treatment carrying fewer risks of misimplementation at the time it is carried out at the work station. In this respect, safety and effectiveness are dimensions that extend to the implementation of a solution.

Eight subjects referred to the need to attain this objective when they design or evaluate a treatment plan.

253 This has two consequences:

the mere availability of a technology is not sufficient to trigger its use. Medical
physicists, physicians and radiographers need to be trained to its appropriate usage. Risks of
inappropriate usage may prevent its actual use. Such sacrifice decisions, in which a suboptimal treatment plan is preferred in order to achieve safety, have been observed, as shown in
the quotation below.

We received the IMRT machine about 18 months ago. The software, however, has been available less than 12 months ago. We have had more and more patients and we haven't had time to develop the IMRT. Knowing the time needed by the IMRT, we will not be able to take as many patients. As a consequence, we devise beam arrangements which are simpler, but also safer for us. P6, Center E.

- solutions vary in their degree of complexity in the implementation stage. An effective
treatment plan may be risky in terms of the required level of precision, of the number of
factors to take into account, in the degree of constraint for the patient, etc.

267	We sometimes have a tendency to try to design a treatment that is perfect on a virtual level, but
268	which will be difficult to execute at the workstation. That is something we must keep in mind. P4,
269	Center D
270	

Thus, a second type of trade-off appears. The good solution in radiotherapy is the one that provides an optimal answer to the medical stipulations (effectiveness) while minimizing risks of implementation (safety).

- 274
- 275 3.2 Effectiveness-safety trade-offs

Although the intent to find an optimally effective solution is clearly present amongst medical physicists, the solution is not always easy to implement. The quest for optimization thus becomes the object of a trade-off determined by two main conditions: the resources that the physicists have at their disposal and the technical feasibility of achieving the solution.

The quest for dosimetric effectiveness through innovative techniques is not always carried out without safety risks for the execution of the solution. According to some subjects, the more sophisticated the techniques involved in a solution, the more it will be prone to risks, despite the presence of automatic checks.

284You can obtain super sophisticated doses, with 10 beams of radiation, non coplanar things, but the285more sophisticated the things you do, the greater the risk of error. P7, Center A

286

In these situations, the ideal solution for a safe and effective treatment cannot beimplemented:

Either one reduces the risks in executing the solution, but then there is loss in
effectiveness. This type of compromise is chosen by a few subjects (3/14) who, although
aware of the loss in terms of treatment effectiveness, give priority to a gain in safety:

292 293 For my part, I prefer a very simple, old-fashioned treatment - something that was already being done 20 years ago, with a square field, and which is perhaps not optimal, but which I know has

294 295

296

It is to be noted that physicist P2 is a young, well-trained professional who belongs to a center which possesses high-performance equipments. P2's preferences are thus not related to lack of training or to an acquired tendency to stick to old-fashioned techniques.

300 - ... or one maintains the effectiveness of the treatment, despite the increased risk of
301 mis-implementation when the solution is carried out.

This last type of compromise is favored by the majority of the subjects (11/14). It involves accepting certain risks, which need to be taken into account when implementing the solution, in exchange for the certitude of the clinical effectiveness of the treatment.

305If we can do something that is optimal and it is possible to implement it, even if it is going to be306difficult, we do it. At least in the cases I've seen up to now, that's what we have always done. For307the moment, it is more the effectiveness of the treatment that is important, even if it is longer and308more complicated at the work station. We prefer to spend more time on it, as long as it is for the309good of the patient. P11, Center B.

310

Nevertheless, the analysis of the data indicated that strategies were employed by physicists to enhance effectiveness and safety of treatments. Actually, physicists have some means of control at their disposal in order to deal with the risks. These involve anticipating the difficulties of execution which the radiographers may encounter and setting up strategies to prevent risks, thus allowing them to control the optimal effectiveness and safety of the treatments. The next section presents these risk prevention strategies.

317

## 319 3.3 Prevention strategies designed to guarantee quality care in radiotherapy

When medical physicists consider the solution to be risk-prone, they anticipate the risks. The subjects were unanimous in mentioning strategies aimed at facilitating the work carried out by the radiographers at the end of the treatment chain, and thus to reduce the risk of misimplementation.

324	On paper, you can be under an illusion of precision. Obviously, on paper the cuts don't move, the
325	patient doesn't breathe, all is well. But in reality, this is not the case, and that has to be taken into
326	account. P7, Center A

327

To do this, they use of two main types of prevention strategies that allow them to act upon the criteria for the safety of the treatment in order to approach the desired optimal effectiveness: avoiding the risks and assisting the radiographers (see Table 2).

331

### 332 *3.3.1* Avoiding the risks

333 Once the virtual design for an optimal solution has been produced, the criteria that the 334 subjects most often refer to are those that take into account the sources of risk in 335 implementing the solution. The aim of verifying these criteria is to ensure that a virtual 336 design for an optimal solution will still be optimal in a real situation. Indeed, physicists 337 reduce the factors that could lead to errors at the source - i.e. the virtual planning stage either by avoiding the use of "high-risk" work stations (ones that have an overload of patients, 338 339 old machines or new radiographer) for complicated treatments, or by limiting the complexity 340 of certain parameters of radiation. In addition, physicists can try to improve the comfort of 341 the patient in order to keep them from moving in a way that would compromise the correct 342 delivery of the dose to the prescribed volume. Thus, the physicists check the conformity of at 343 least three sources of risk: the technical factors, the human and organizational factors, and the

344 p	oatient.
344 p	oatient.

345	We will try to limit the variety of filters because that is a regular source of error: a $30^{\circ}$ filter
345	we will try to timil the variety of filters because that is a regular source of error. a 50 filter
346	instead of a 45° filter, and so forth, that sort of thing. Sometimes we say to ourselves: instead of
347	having 5 beams we will try to stay with 4 and adjust other elements. Because you have to go into
348	the room every time, you have to change the shields. And the precision in positioning the shields
349	is not as good as it could be with multileaf collimator (a pair of independent blades used to define
350	a beam with a complicated shape). P4, Center D
351	
352	Half of the physicists mentioned that they adjust certain radiation parameters to avoid
353	"confusing" the radiographer or to facilitate their work. The means used are designed
354	especially to reduce the time involved in manipulation and to minimize errors commitment.
355	For example, for positioning the patient backwards or forwards on the table, we try never to put
356	2.38 cm, we put 2.5 cm. We will round off to half a centimeter so that radiographers won't make a
357	mistake. P2, Center A
358	
359	Along with these strategies, other strategies are destined to help the radiographers carry out
360	the treatments safely and effectively. They are listed below.
361	
362	3.3.2 Assisting the radiographers
363	The strategies for assisting the radiographers include not only oral and/or written transmission
364	of solution designs, but also the presence of physicists or dosimetrists by the operator's side
365	when the solution is first implemented. These strategies aim to control the sources of risk that
366	were not already taken into account during the virtual conception.

#### 368 *The oral and/or written transmission of solution designs*

In all, 13 of the 14 physicists mentioned that when a solution is complicated or unusual, the routine instructions for implementing the treatment that are provided in the file are reenforced, and any possible changes are indicated. This is a way of anticipating certain difficulties that the radiographers could encounter during a treatment session.

376	going to have a bit of trouble, but it is for the good of the patient". <b>P10, Center E</b>
375	of the way the target is, I can't treat it with a classic technique, so I prefer to warn you that you are
374	treatment where there are only oblique beams, so it's complicated". But I tell them why: "Because
373	For the complicated cases, I go see the radiographers and I say to them "Look, I've planned a

377

## 378 <u>Presence during the first implementation of a complicated solution</u>

For the non-standard cases, giving instructions alone is not sufficient to reduce the risks involved in carrying out a complicated solution. As a matter of fact, nine of the 14 subjects mentioned that one of the ways to reduce the complexity of a solution was to be present for the first implementation, that is, to be present in the x-ray room with the radiographers, in order to better control the risks.



387

388 The identified risk prevention strategies used by medical physicists and discussed previously389 are presented in Table 2.

NG PATIENT SAFETY		Accounting for technical factors (n=8)	Type of machine	Avoid sending complicated treatments to old work stations Limit the complexity of manually controlled radiation parameters
ENHANCI			Radiation parameters	Adjust certain risk-prone parameters despite presence of automatic controls
			Quality and type of	Take into account to determine
			contention	length of session
	Avoiding risks Taking human and organizational factors into account (n=6) Taking patient comfort into account (n=6)	Taking human	Radiographers' experience	Avoid sending a complicated treatment to a work station where the radiographers are novices
		Workload at the station	Avoid sending a complicated treatment to a work station where there is an overload of patients	
		(n=6)	Quantity of complicated cases per day	Avoid sending a complicated treatment to a work station where there is a large number of complicated treatments per day
		Taking patient comfort into account (n=6)	Position difficult to maintain/Patient suffering from pain/Children	Avoid positions that are difficult to maintain for a long period, especially for patients suffering from pain or for children
	Assisting	Oral or written	Warning messages indica	ating a non standard treatment

г				
		Radiographers	transmission	Instructions indicating a call for help
				a a a a a a a a a a a a a a a a a a a
			(n=13)	
			(11-13)	Instructions for positioning
				1 0
			Presence of the	
			medical physics	Oral instructions, verification of the reproducibility of the
				or an instructions, vormounted or and reproductionity or and
			team	simulated positioning
			(n-9)	
			(11-5)	
391			Table 2 : Risk	prevention strategies
202				
392				
000		<b>D</b> I I		
393	4.	Discussion		
394				
395	5 4.1 Strategies for maximum performance			

The diagram shown in Figure 1 summarizes the main findings from the study, i.e. the applicability of an ideal solution and the possible compromises with regard to this ideal solution.



Figure 1 : Diagram of the applicability of an ideal solution

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400

402 We should note in this Figure that, in the absence of resources, the search for a compromise is 403 not a matter of choice for the medical physicists. They are obliged to abandon the quest for 404 an ideal solution and to be content with a solution consisting of a satisfactory compromise. If 405 the ideal solution is possible with the available resources, the physicists will seek to achieve 406 optimal effectiveness with this solution. Thus, the optimal solution is always a local one: it is 407 resource-dependent. In the presence of risks, the majority of physicists will pursue the quest 408 of maximum effectiveness, because they have a certain number of strategies allowing them to 409 take action to prevent risks. Nevertheless, even though they take a calculated risk, it is a risk 410 all the same. This implies a certain degree of compromise on safety, and confirms the 411 presence of a very specific characteristic of the medical profession, i.e., the quest for optimal 412 performance in terms of treatment effectiveness (Amalberti, Auroy, Berwick, & Barach, 2005;
413 Woods, 2006).

We have seen that a minority of subjects will not take this risk (3/14). This decision may be due to an absence of the resources necessary for ensuring the safety of a risk-prone optimal effective solution. Some subjects will therefore prefer to compromise on effectiveness and return to a safer, more classic solution.

418 4.2 Errors, effectiveness and safety

419 The notion of error does not have the same meaning when considering the two criteria and420 when considering the trade-off between the two criteria.

421 - In the effectiveness context, an error is a treatment plan that fails to optimally
422 distribute the dose according to the standard (95% in the prescribed zone, as little irradiation
423 as possible in the organs at risk).

424 - In the safety context, an error is an inaccurate implementation of the treatment plan:
425 failure to set a protection device, wrong duration of the irradiation, wrong positioning of the
426 patient, etc.

427 - In the effectiveness/safety trade-off, an error can be :

either the choice of a treatment plan that may lead to safety errors when these potential
errors are not foreseen and protected by prevention barriers devised by the physicist
(dangerous trade-off);

o or the choice of a treatment plan that is perfectly safe but suboptimal in terms of
effectiveness (ineffective trade-off).

433

## 434 4.3 Informal safety practices that should be encouraged

435 The physicists' strategies reveal that they take into account their colleagues' activities when

436 carrying out their own activities. This constitutes a guarantee of cooperation in the interest of 437 safety (Manser, 2009). The physicists' objective is to make sure that the virtual optimal 438 solution will be optimal in real situations. However, this activity remains "invisible" inside 439 the organization, and therefore, unrecognized, even though it is costly in terms of time: time 440 for implementing the risk reduction strategies, and time for being present to assist the 441 radiographers. Thus, as soon as the organization has a sufficient number of physicists 442 available, it must calculate the amount of time that can be allotted to this type of safety work. 443 An awareness of the work other people carry out in the interest of enhancing safety must also 444 be shared by all the actors involved, including during the period of their initial training, in order to maintain a common level of awareness about the importance of the work of the whole 445 446 group for the work of each individual.

447

## 448 4.4 Limits of the study

449 In order to investigate the compromises under study, a semi-experimental method was used, 450 which exclusively focused on the medical physicists' point of view. It would have been useful 451 to observe conversations between physicists and physicians when discussing compromises for 452 difficult solutions. This would have allowed us not only to analyze the content of the different 453 exchanges and compare the differences between various physicist-physician teams, but also to 454 study the same physicist in relation to the different physicians he/she is dealing with. These limits could be taken into account in a study of the points of view of the physicians and of 455 456 physician-physicist teams when conflicts arise between the effectiveness and the safety of a 457 treatment.

458

#### 459 **5.** Conclusions

In cases of conflict between the effectiveness and the safety of a solution, the majority of the 460 461 physicists give priority to effectiveness, achieved by means of a treatment plan. In designing 462 this solution, the ease of execution for the radiographers is not a factor that is taken into 463 consideration. Safety is handled in a second step, by facilitating or assisting the 464 implementation of the treatment. In particular, the results show the important role of oral and 465 written transmissions, and of the presence of a physicist/dosimetrist at the radiation 466 workstation when complicated treatments are administered. These strategies are shared by the 467 majority of physicists and are a sign of a strong culture of effectiveness, based on the 468 optimization of medical protocols and associated with a culture of safety, founded on the 469 prevention of risks at the workstation. The former is prescribed by the formal rules of 470 radiation, while the latter is not formalized and belongs to the realm of practical knowledge 471 about the radiographers' situations, organization and work.

472 Thus, obtaining patient safety via risk management, as it is implemented by medical 473 physicists in radiotherapy, is much like that observed by Amalberti (1998) when he developed 474 the concept of ecological safety. In this perspective, risk management undergoes a metacognitive evaluation<sup>3</sup> that gives the operators the sense that they master the situation. 475 476 During this evaluation, they take into account the objective risks that are attached to the 477 consequences of errors, and the internal risks, i.e. the consequences of not being up to the task 478 (Amalberti, 1998). This allows them to target maximum performance, that is to say the 479 production of effective treatments, while at the same time providing barriers for controlling 480 the previously identified risks.

481 Adverse outcomes are too frequently attributed to those who provide radiotherapy. Contrary482 to this, the findings of this study indicate consistent concern for and efforts to enhance patient

<sup>&</sup>lt;sup>3</sup> The Oxford Dictionary of Psychology (2003) defines metacognition as knowledge and beliefs about one's own cognitive processes (cognition about cognition). In our case, a metacognitive evaluation allows subjects to assess their awareness of the management of risks and their ability to adapt to challenges that occur during this process through effective strategies

483 safety while providing effective treatment by those who plan and implement radiotherapy.
484 Thus, when an adverse outcome occurs, rather than automatically blaming the technician,
485 others possible contributing factors, such as the design of the radiotherapy device, are
486 candidates for consideration.

487

#### 488 Acknowledgements

489 The authors wish to express their gratitude to the operators who participated in this study. This

490 work was supported by a Ph.D grant from the Ministère de l'enseignement supérieur et de la

491 recherche and the Service d'Etudes des Facteurs Humains de l'Institut de Radioprotection et

492 Sûreté Nucléaire (IRSN). The authors would also like to thank Dr. Vanina Mollo for her

493 valuable comments on this study.

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