## Lean Thinking to manage a national working group on physics aspects of Stereotactic Body Radiation Therapy

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**Purpose:** To report how the adoption of a Lean Thinking mindset in the management of a national working group (WG) on the physics of stereotactic body radiation therapy (SBRT) contributed to achieve SBRT standardization objectives.

**Methods:** Vision for the WG has been established as fragmentation reduction and process harmonization enhancement in SBRT for Italian centers. Two main research themes of the technical aspects of SBRT emerged as areas with major standardization improvement needs, small field dosimetry and SBRT planning comparisons, to be investigated through multi-institutional studies. The management of the WG leveraged on the Lean concept of fostering self-organization in a non-hierarchical environment. Four progressive involvement levels were defined for each study. No specific "scientific" preexperience was required to propose and coordinate a project, just requiring a voluntary commitment. People engagement was measured in terms of number of published articles. The standardization goals have been conducted through a simplified "5S" (Sort, Set in Order, Shine, Standardize, and Sustain) methodology, first considering a phase of awareness (the first three "S"), then identifying and implementing standardization actions (the last two "S").

**Results:** Since the beginning, 157 medical physicists joined the AIFM/SBRT-WG. Twenty-four papers/reviews/letters have been published in the period 2014–2019 on major radiation oncology journals, authored by >100 physicists (>50% working in small hospitals). Six over 12 first authors worked in peripheral/small hospitals, with no prior publication as first author. These studies contributed to the awareness and standardization phases for both small-field dosimetry and planning. In particular, errors in small-field measurements in 8% of centers were detected thanks to a generalized output factor curve in function of the effective field size created by averaging data available from different Linacs. Furthermore, planner's experience in SBRT was correlated with dosimetric parameters in the awareness phase; while sharing median dose volume histograms (DVHs) reduced variability among centers while keeping the same level of plan complexity. Finally, all the dosimetric parameters statistically significant to the planner experience during the awareness phase, were no longer significantly different in the standardization phase.

**Conclusions:** The experience of our SBRT-WG has shown how a Lean Thinking mindset could foster the SBRT procedure standardization and spread the physics of SBRT knowledge, enhancing personal growth. Our expectation is to inspire other scientific societies that have to deal with fragmented contexts or pursue processes harmonization through Lean principles. © 2021 American Association of Physicists in Medicine [https://doi.org/10.1002/mp.14783]

Key words: 31.13 (31: TH- External beam- 13: photons extracranial stereotactic/SBRT), Lean Thinking, SBRT, taxonomy index, working group management

### 1. INTRODUCTION

In the last decades, stereotactic body radiation therapy (SBRT) has been introduced for treating small targets in few fractions of extremely high dose. Its clinical value in terms of high tumor control and low toxicity profile has been demonstrated in numerous studies for both primary and metastatic settings.<sup>1–3</sup> Furthermore, more recently, international consensus on implementation and practice of SBRT in different regions are appearing in literature.<sup>4–6</sup> The adoption of SBRT is growing year by year and many centers worldwide are implementing it. Early clinical studies were typically performed in academic centers within controlled trials.<sup>7</sup> Nevertheless, SBRT is nowadays regularly performed in non-university hospitals, too.<sup>8</sup>

The geographical conformation of Italy (i.e., long and narrow) has contributed to the presence of several centers with only one or two linacs, with few medical physicists and consequent limited preparation on specific topics such as the dosimetric aspects of SBRT. To facilitate the creation of a network to overcome geographical barriers, a dedicated working group (WG) within the Italian Association of Medical Physics (AIFM) was started in 2013, in order to support on a national level — the standardization of dosimetric and planning aspects of SBRT (AIFM/SBRT-WG). Standardization-related objectives then fostered the idea of adopting "Lean Thinking" as an approach to inspire the WG way of work, being optimization among the crucial elements of the so-called "House of Lean."<sup>9</sup>

The word "Lean" became popular thanks to Womack et al.,<sup>10</sup> first as an extension to manufacturing in general of the "Toyota Production System" approach, created by Ohno.<sup>11</sup> A subsequent evolution of Lean on an enterprise level was introduced in 1996, as "Lean Thinking."<sup>9</sup> Lean could be considered as a systematic attitude to remove different types of waste (or *Muda* in Japanese) that yield to nonvalue added activities. In Lean adoption to healthcare, and more in general to manufacturing, a particular possible waste is added: human potential, to describe when frontline healthcare workers are not engaged, heard, or supported<sup>12</sup> and stop sharing ideas for improvement. Recently, Lean approaches were applied to radiotherapy departments, too.<sup>13–16</sup>

The aim of this paper is to report how the adoption of a Lean Thinking mindset in the management of the AIFM/SBRT-WG contributed to achieve SBRT standardization objectives.

### 2. MATERIALS AND METHODS

The WG-coordinator, in agreement with the AIFM President, proposed a Lean Thinking-inspired approach to manage the WG, leveraging the Lean principle of valorizing own personal skills to increase efficacy ("building people before building cars"<sup>11</sup>). Vision for the WG has been established as fragmentation reduction and process harmonization enhancement in SBRT for Italian centers. Personal awareness increase and knowledge sharing have been considered as founding elements to achieve such a Vision. The opening manifesto (November 2012) is reported in Supplementary Materials (Section A). Two main research themes of the technical aspects of SBRT emerged as areas with major standardization improvement needs, small field dosimetry and SBRT planning comparisons, to be investigated through multi-institutional studies.

While refining the Vision, a working framework has been defined, in terms of approach, roles and lifecycle of projects born in the WG context.

Leveraging the Lean concept of fostering self-organization in a non-hierarchical environment, four progressive

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involvement levels have been defined as roles in each project: principal investigator, co-investigators, workers, and followers. No specific "scientific" pre-experience was required to propose and coordinate a study as principal or co-investigator. The only constraint was in terms of engagement: all roles were self-assigned, but required the voluntary commitment to be maintained through the entire project duration.

To set a context to enhance standardization and facilitate volunteering to one or more proposed projects, each one was summarized in terms of: overview, aims, actions, timing, expected benefits. An example of a proposed study is reported in Supplementary Materials (Section B). A project was considered accomplished once the experience, contributing to the standardization of SBRT procedure, had been shared both within the WG (during meetings or in newsletters) and externally (through submission on international journals of articles, systematic reviews and letters to the editor on specific SBRT topics): this was the "Definition of Done" agreed among the participants. The AIFM President was consulted and the WG coordinator remained accountable for insuring continuity between the selected studies and the aims and policy of the national scientific society.

The two Lean concepts mostly inspiring the management of the WG were: *Jidoka* (as a way to reach built-in quality, humanly interrupting automated flows as an anomaly emerges) and *Kaizen*<sup>17</sup> ("change for the better" as conceptualized in Toyota Production System, a form of continuous improvement toward quality, waste reduction, and process excellence, in a team dimension as well as in a personal one).

In addition to being in line with the objectives of the WG, Lean Thinking suggested techniques to let standardization opportunities emerge. Among Lean optimization tools, we considered a simplified "5S" methodology. The term "5S" refers to the initials of five Japanese words (*Seiri, Seiton, Seiso, Seiketsu,* and *Shitsuke*, that can be translated in English as Sort, Set in Order, Shine, Standardize, and Sustain). WG approach to small-field dosimetry and planning standardizations could then be considered composed of two phases: awareness (the first three "S") and standardization actions (for the last two).

Two kinds of results are presented hereafter: (a) how a *buy-in* (active involvement) by AIFM members has been fostered, with related Lean-inspired metrics, and (b) the path toward optimization goals in small field dosimetry and planning standardizations.

### 3. RESULTS

### 3.A. Employees' buy-in

The birth of AIFM/SBRT-WG was promoted by inviting, through periodic newsletters, all members of the national association (more than 1200) interested in deepening medical physics aspects of SBRT. New joiners confirmed their involvement through a web-based subscription on the national AIFM website. Fifty-three medical physicists attended the first foundation meeting. The number grew up to 157 medical physicists from more than 80 Italian centers, covering half of the SBRT Italian centers (163 centers — from www.radioterapiaitalia.it). The *buy-in* was also enhanced by performing dedicated courses on the basis of SBRT. All courses were delivered as joint symposiums on SBRT, with a faculty that included both medical physicists and radiation oncologists to support comparison and sharing between different professions. Supplementary Materials (Section C) contains a course summary as an example. More than 500 medical physicists and radiation oncologists participated to the courses.

### 3.B. Engagement metrics

Twenty-four papers/reviews/letters have been published on top 50% ranking Radiation Oncology journals in 2014–2019 period,<sup>18–40</sup> with authors list selected according to Vancouver recommendations. In detail, 15 full papers.<sup>19–23,28–32,34–36,38,40</sup> 5 reviews,<sup>18,27,33,37,41</sup> 1 editorial,<sup>25</sup> and 3 letters to the editor<sup>24,26,39</sup> were published. A total of more than 100 medical physicists were authors of at least one article, showing high level of members' engagement. In particular, more than 50% of the authors worked in centers with one or two linear accelerators. The first multi-institutional projects involved a few centers. The number grew, reaching 38 centers involved in the latest SBRT multiplanning project,<sup>23</sup> to our knowledge the largest non-sponsored study worldwide.

Table I shows the list of the principal investigators (i.e., first authors of the papers). In particular, 6 out of 12 main authors (50%) worked in peripheral/small hospitals, without previous scientific experience (i.e., no prior publication as first author).

Moreover, in these years, the WG performed many international activities (Supplementary Material, Section D), including a couple of collaborations with Germany and Spain.<sup>18,21</sup>

Author initials	# times as the first author before joining WG	# times as the first author within WG
GF	0	3 <sup>18,27,32</sup>
RS	0	3 <sup>20,29,34</sup>
EM	0	3 <sup>23,35,41</sup>
МС	0	2 <sup>19,38</sup>
CE	0	1 <sup>30</sup>
VE	0	1 <sup>21</sup>
MP	>3	5 <sup>25,26,28,33,39</sup>
CS	>3	2 <sup>37,40</sup>
ML	>3	1 <sup>31</sup>
GC	>3	124
VI	>3	1 <sup>36</sup>
TC	>3	122

# 3.C. Optimization goal: Small field dosimetry standardization

Among the goals of the WG, a reduction of systematic errors in small field output factor evaluation emerged as a prior factor to be analyzed and addressed. The first studies aimed to validate — through new generation detectors measurements — the output factor measurements for small fields performed by detectors available in each center. The results of this first phase highlighted the differences in output factors as a function of nominal field size using different detectors [awareness phase — see Fig. 1(a)].  $^{28,29,34}$  The next step was to generate specific output factors curve using effective field size for specific Linac [Truebeam<sup>30</sup> — see Fig. 1(b)] or robotic Linac CyberKnife<sup>20,31</sup> (standardize phase). As a final step we generalized a relative signal ratio curve in function of effective field size by averaging data available from different Linacs,<sup>22</sup> adopting a crowd knowledge based approach see Fig. 1(c)]. Such a sharing method was defined in our papers<sup>26,39</sup>: no predefined hierarchy among datasets from different centers is identified, as happens in the typical teacher/

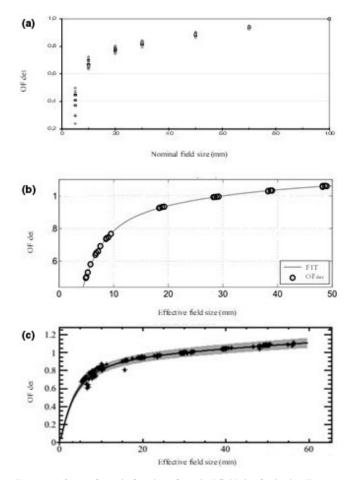


FIG. 1. (a) Output factor in function of nominal field size for 8 miscellaneous Varian Linacs (modified by Russo et al.<sup>29</sup>); (b) Output factor in function of effective field size for 4 Varian TrueBeam (modified by Cagni et al.<sup>30</sup>); (c) Output factor in function of effective field size for 24 multi-vendors Linacs (modified by Talamonti et al.<sup>22</sup>).

student relationship where it is declared *a priori*, but the results dynamically regulate the hierarchy. Following this approach, points more than  $\pm 5\%$  away from the reference curve were reconsidered. Two centers (over 24; i.e., 8%) presented three values greater than 5%. The two centers repeated their measurements and new data resulted in a narrower deviation distribution.<sup>22</sup> Therefore, the sharing of small field dosimetric data allowed to harmonize the expertise of different radiotherapy centers and helped the data standardization, providing a consistent dataset that could be used as reference for on-site measurements validation.

### 3.D. Optimization goal: Planning standardization

We aimed to reduce the intra-variability in SBRT planning. The first studies aimed to quantify the dose–volume histogram (DVH) difference of different planners (awareness phase). At this aim, multi-planning studies on liver,<sup>35</sup> lung,<sup>32</sup> and prostate<sup>38</sup> were performed. Medical physicists planned the same patients contoured by a single radiation oncologist using a common shared protocol. In the standardization phase, the DVHs were shared and a new plan was generated starting from the previous DVHs (see Fig. 2). This helped in reducing the constraints violations using the median results obtained by all participants.<sup>23</sup> Furthermore, an analysis of the planner experience was assessed on prostate SBRT over 13 centers.<sup>21</sup> Many parameters were considered. Planner's experience in prostate SBRT was correlated with dosimetric parameters in the awareness phase. Sharing median DVHs reduced variability among centers while keeping the same level of plan complexity. The results between the two phases were compared using the Kruskall–Wallis test. All the dosimetric parameters statistically significant to the planner experience during the first phase, were no longer significantly different in the standardization phase. For a deeper explanation we refer to the specific paper.<sup>21</sup>

### 4. DISCUSSION

To our best knowledge, this is the first time a Lean Thinking approach has been applied for the management of a scientific WG in medicine field.

Lean in healthcare has been used to improve the employee and patient gratification, health and procedure results, and financial costs. Two systematic reviews found Lean interventions in healthcare to focus mainly on process results.<sup>42,43</sup> Nevertheless, a recent paper stated that the impact of Lean in healthcare quantification should require higher scientific

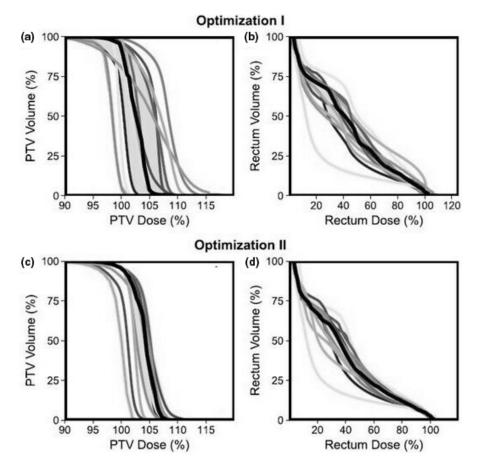


Fig. 2. Dose–volume histograms (DVH) curves for PTV (a) and rectum (b) for a prostate plan optimized with VMAT by 13 centers. The black curve represents the DVHs averaged over the centers. In the optimization II, the planners visualized the previous DVH curves (a, b) to optimize the target (c) and rectum curves (d). Modified from Villaggi et al.<sup>21</sup>

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approach.<sup>44</sup> Lean principles engage health-care professionals to improve safety and quality in the provided services. In addition, Lean requires managerial commitment to be effective: in SBRT WG the full sponsorship of AIFM President represented an immediate Leadership *buy-in*. An institution could adapt Lean's instruments to its specific working framework as part of a global managing system that merges process enhancement to culture change, innovative leadership, and empowerment of its frontline professionals.<sup>45</sup> D'Andeamatteo et al. reported Lean to be promising in healthcare, however, findings did not let to demonstrate the impacts in this sector.<sup>46</sup>

In our scenario, fragmentation has been the main driver to embrace *Kaizen* ("change for the better" in Japanese), but the resulting engagement in scientific community contribution showed the effectiveness of a Lean approach regardless of the starting maturity of the context.

In this study, we measured the effect of people engagement by evaluating the number of articles published by WG members on peer-reviewed journals. The peer review process could represent a challenge for professionals with little familiarity with scientific writing: it requires deep knowledge of the topic, as well as scientific method. Considering the papers published in 2019, five out of six (i.e., 83%) were written by authors without previous experience, sign of the ability to engage colleagues at the highest scientific level. Therefore, the activity of the WG allowed professionals without previous publications of scientific papers to capitalize on their experience in the field. The publication on scientific journals contributed to the procedure standardization and, at the same time, enlarged the engagement around the national community, creating an awareness against human potential waste.

Quality has been a major component of radiation therapy since its beginning. Enhancing the safety of the therapy is still challenging. Radiation oncology practice is characterized by deep interactions between human activities and mechanical tasks, produced by sophisticated software and hardware technologies. Furthermore, several health specialists are involved, and several contacts take place among health experts and patients. In particular, an SBRT procedure, with high dose per fraction is especially tricky and medical physicists could play a major role in supporting radiation oncologists, as being involved in many parts of the procedure.

The earliest application of Lean in radiation oncology was reported by Simons et al.<sup>13</sup> The authors quantified the impacts of Lean interventions on the patient safety in radiotherapy department. Authors showed that the treatment process redesign improved the patient safety. Radnor et al. stated that Lean in healthcare typically includes the usage of specific Lean "tools," which could produce only localized productivity gains.<sup>47</sup> Simons et al. showed that the implementation of 15 Lean interventions led to the reduction of waiting times in a RT department from 20 to 16 days.<sup>15</sup> Mancosu et al. recently reported the application of Lean Six Sigma methodology to improve the image-guided radiation therapy (IGRT) of breast cancer patients.<sup>16</sup> SBRT was initially performed to patients with poor performance status. Thanks to the promising results, SBRT has now enlarged in operable patients. The technological progress in radiation oncology played a major role in this success and greater precision in the delivery of radiotherapy has allowed the treatment of more difficult cases, which means that a greater number of patients candidates for a SBRT treatment.<sup>4–6</sup> Moreover, the adoption of SBRT is no more exclusive of large academic centers and small centers could need help in implementing the physics of SBRT.<sup>8</sup> The challenge of this WG was to help medium/small centers in the physics implementation of this technique. The multicenter studies carried out by the AIFM/SBRT-WG focused on two main different topics: small field dosimetry and SBRT planning.

New small field dosimetry formalism was introduced by Alfonso et al. in 2008.<sup>48</sup> The correction required for determining the beam output factor in small field conditions were not yet calculated at the time of the AIFM/SBRT-WG opening manifesto, despite the growing accessibility of detectors acclaimed as appropriate for measurements in the small fields sector. The dosimetry studies conducted by the AIFM/SBRT-WG had the explicit aim to reduce systematic errors in output factor evaluation by data sharing over different radiotherapy.

By the time the working group started, consensus on the normalization of the SBRT plan had not yet been reached. ICRU 83 for IMRT management recommends prescribing at the mean dose, limiting the hotspots and maximizing the target coverage.<sup>49</sup> AAPM TG-101 recommends prescribing the dose at the periphery and allowing dose of 120% of the periphery dose in the target center.<sup>50</sup> ICRU 91 recommends to report mean near maximum and near minimum doses but no indication on the homogeneity level request was provided.<sup>51</sup> Our results demonstrated that a crowd-based re-planning approach is a feasible technique for accomplishing harmonization and standardization of treatment planning between differently equipped centers.

In conclusion, the experience of the AIFM/SBRT-WG has shown how a Lean Thinking mindset could foster the SBRT procedure standardization and spread the physics of SBRT knowledge, enhancing personal growth. Our expectation is to inspire through Lean principles other medical associations that have to deal with fragmented contexts or work to pursue processes harmonization.

### **CONFLICT OF INTERESTS**

The authors have no conflicts to disclose.

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### SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Section A. AIFM/SBRT-WG Opening Manifesto Section B. Example of a Project design Section C. Example of a course purpose Section D. Other international activities