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# Development, implementation, and associated challenges of a new HDR brachytherapy program

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## ABSTRACT

Developing any new radiation oncology program requires planning and analysis of the current state of the facility and its capacity to take on another program. Staff must consider a large number of factors to establish a feasible, safe, and sustainable program. We present a simple and generic outline that lays out the process for developing and implementing a new HDR brachytherapy program in any setting, but with particular emphasis on challenges associated with starting the program in a limited resource setting. The sections include feasibility of a program, starting cases, machine and equipment selection, and quality and safety. © 2020 American Brachytherapy Society. Published by Elsevier Inc. All rights reserved.

## Keywords:

Brachytherapy; HDR; Quality and safety; Implementing new treatment techniques; International; Limited resource setting

## Introduction

Brachytherapy is an important and often necessary component in the management of patients with various types of cancer across the globe. Cervical cancer is the fourth most common cancer in women worldwide, with most cases occurring in developing countries, and there have been multiple publications regarding the necessity of brachytherapy in the treatment of cervical cancer (1–3). Other cancers might not necessarily require brachytherapy, but it could be a highly effective treatment option that is convenient and cost-effective. In the rapidly evolving world of radiotherapy, there has been an increased utilization of hypofractionation. When given the option, most patients would opt for convenience and a shorter treatment course. Today, the fractionation schedule for accelerated partial breast irradiation using brachytherapy has seen movement from 5 day, 10 fraction courses, to 2 day, 3 fraction courses (4). This reduces the number of trips the patient must make, which can be particularly attractive if the patient must travel far or has other transportation issues. With the

COVID-19 pandemic, fewer treatments decrease contact interactions with others (public, patients, and staff), thereby reducing infection risk. Despite factors and motivation to start a brachytherapy program, many centers are intimidated by the challenges presented with starting a program from scratch. This article is intended to be a practical framework for developing and implementing a new brachytherapy program and, in particular, highlights challenges associated with development and implementation in resource-limited settings. The sections of this framework include feasibility of starting a program, starting cases, machine and equipment selection, and quality and safety.

### *Feasibility of starting a program*

The decision to start a brachytherapy program requires in-depth analysis and determining factors for success. These include significant patient caseload, sufficient space, appropriately trained personnel and acknowledgment of the increased time commitment required to deliver brachytherapy treatments. If any of these are missing, or insufficient, the program will either be unsafe or unsustainable. In this section, we will discuss these requirements in more detail.

### *Case load*

Although brachytherapy can be used to treat a number of malignancies including prostate cancer, breast cancer, skin cancer, and others, by far the most common malignancy

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treated around the world with brachytherapy is carcinoma of the cervix. Brachytherapy use has been shown to improve both local control and overall survival in this disease (2,3). In fact, it is the requirement for brachytherapy in cervical patients with cancer that often leads to the decision to start a brachytherapy program. Typically, in the United States, treatment centers operate with a hub-and-spoke system for providing brachytherapy. This is a health care system with multiple centers where patients requiring brachytherapy are typically sent to a central site that has the equipment and expertise to deliver the treatment. This is both economical and leads to consolidation of expertise and higher quality treatment (5). However, with only 13,800 cases of cervical cancer per year in the United States (6), for a brachytherapy program to thrive, it will be necessary to treat other types of malignancies. The incidence of carcinoma of the cervix is much higher in parts of the developing world, including eastern and central Africa, where it is the most common malignancy (7). In these countries, a single high-dose-rate (HDR) afterloader can easily be overwhelmed by treatment of this single disease.

Because brachytherapy is both a surgical procedure and a radiotherapy treatment, it requires a multidisciplinary approach involving gynecologic oncologists, urologists, surgical oncologists, radiologists, and pathologists to plan and deliver effective treatment and manage situations or morbidity afterward. Having the input of other services will lead to a more coordinated treatment approach and likely better outcomes. Moreover, involvement of other specialists outside of radiation oncology will increase the visibility of the service and likely lead to a greater case load.

In 2020, the average cost of an HDR afterloader ranges from USD 200,000 to USD 350,000 with ongoing annual service/source exchange costs of well over USD 20,000/year. Considerations of cost are quite different in the United States as compared with low- and middle-income countries (LMICs) and are beyond the scope of this article. Careful consideration to cost and case load in the evaluation of sustainability is essential. Radiating Hope, a charitable organization that provides radiation therapy equipment and training to clinics in the developing world, has donated a number of HDR units across the globe. It is tempting to think that these facilities will not have the same financial pressures and required case load to sustain the equipment. However, the cost of ongoing maintenance of the afterloader, source exchanges, and replacement of applicators are expensive endeavors and sources of funding such as charitable donations, home country support, or clinic buy-in must be in place to cover these expenses to avoid jeopardizing the entire program.

#### *Sufficient space and resources*

Consideration of the HDR suite is very important in the planning process. An HDR afterloader requires a stable power supply and the room requires sufficient shielding.

Shielding requirements depend on the isotope (greater for Co-60 than for Ir-192). Although it is convenient to install the unit in an existing EBRT room due to the substantial cost of building, a separate HDR vault doing so may limit the growth of the program because of limited treatment time. A high-volume brachytherapy center should have a separate HDR treatment room. This room should have sufficient space for the patient gurney, brachytherapy team, and any surgical or anesthesia equipment. It should also be equipped with emergency equipment such as a shielded source storage container (pig) and it should contain, or be located in close proximity to, the imaging equipment appropriate for the type of treatment planning being performed.

#### *Training and personnel*

Appropriately trained personnel are often a prohibitive factor in the development of an HDR program. The American Association of Physicists in Medicine (AAPM) Task Group-59 report recommends that the treatment team consist of a radiation oncologist with special expertise in brachytherapy, preferably HDR; a medical physicist with expertise in brachytherapy who receives at least vendor-supported onsite training on the treatment machine and planning system; and a treatment-unit operator who could be either the physician, physicist, dosimetrist, or a radiation therapist (8). The International Atomic Energy Agency (IAEA) also indicates that nursing staff is among the minimum personnel required (9). We strongly endorse this recommendation as these are surgical procedures that require substantial patient monitoring. In LMICs that do not currently have HDR brachytherapy, the radiation oncologist will often have training and experience in low-dose-rate brachytherapy and the placement of applicator devices may be straightforward. However, additional training is required to obtain expertise in dose prescription, radiobiological differences between low-dose-rate and HDR, and emergency procedures. It may also be difficult to find a physicist with sufficient experience in countries where HDR is not currently being performed. Physicists who perform brachytherapy require training in afterloader procedures, treatment planning, and quality assurance procedures. All members of the treatment team should be trained in emergency procedures. Competency assessment should be included as part of the training of personnel for new procedures and will be discussed further in Section 4: Quality and Safety.

Any time a new treatment site is added, additional expertise is needed. For example, a center that treats gynecologic (GYN) cases regularly may wish to add prostate brachytherapy or another disease site. Although training in afterloader use, quality assurance protocols and safety procedures is likely universal to all disease sites, expertise in treatment planning, treatment techniques and dose constraints may require additional training.

### Time commitment

Because of the substantial time commitment required, it would not be possible to start an HDR brachytherapy program without a dedicated team whose time is not already occupied with external beam radiation therapy. A GYN brachytherapy procedure can take from 60 min up to 3–4 h. It is impossible for team members to be involved in other unrelated tasks during that time. Any center planning to implement HDR brachytherapy should understand that it will put a substantial demand on resources. This is the same reason we recommend that the afterloader not be installed in an existing, active EBRT vault.

Key points on feasibility of starting a program: It is essential to perform a careful analysis of the current state of the clinic and factors needed to start a new program. Physical space, financial resources, personnel, time, and training are all important factors in determining feasibility. Any weakness in these components represents a serious impediment to starting or sustaining a program.

### Starting cases

When beginning the program and picking the first patient/case, choose a reasonable time frame for equipment acquisition, training, acceptance and commissioning, and other tests or practice runs. Even patient selection for the first few treatments is important, and our recommendation is to start with relatively simple cases.

### Cylinders

One of the most straightforward and best treatments for beginners is the vaginal cylinder (Fig. 1). These are used for postoperative endometrial cases to treat the vaginal cuff and are very common in the United States where endometrial cancer cases outnumber cervical cancer cases. The vaginal cylinder is composed of a single channel that is inserted in the vaginal canal. With fixed geometry applicators like a cylinder, computer template plans can be used to deliver a standard dose with a combination of active length, cylinder diameter and depth of prescription. This type of treatment allows the center to gain experience with an HDR procedure, planning, and patient management, paving the way to more complex treatments in the future.

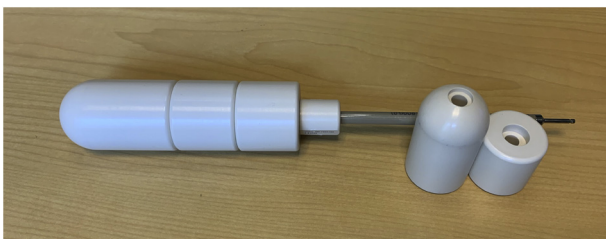


Fig. 1. Example of a segmented cylinder applicator.

### Tandem and ring and tandem and ovoid

The next step would be to implement tandem and ovoids/ring (Fig. 2) for cervical cancer as these patients comprise a large portion of the patient population, especially in LMICs. A tandem and ring (T&R) is composed of an intrauterine tandem and a ring that sits against the cervix in the vaginal fornices. Most T&R applicators have a rectal retractor that allows the user to push the posterior vaginal wall posterior and add space between the applicator and rectum, reducing rectal wall dose. The T&R has a fixed geometry, so with proper training, template plans can also be used when treatment planning is limited in LMICs. In Dakar, Senegal, where HDR was installed without a functioning treatment planning system, the cervical cancer brachytherapy program was developed around the T&R applicator with a library of plans and doses prescribed to Point A. Isodose overlays were created for 2D radiographs to estimate bladder and rectal doses for determination of adequate geometry and normal tissue sparing (10).

The tandem and ovoid (T&O) is another applicator that can be used for cervical cancer treatment, which gives more flexibility in implant geometry, but requires packing instead of the rectal retractor. The simplest T&O treatment planning process is filming 2-dimensional radiographs and locating Point A and rectum and bladder points. This does not require expertise in contouring and the treatment dwell times are relatively standard. A center could start with this technique until they have enough experience and training in contouring to begin image-guided brachytherapy utilizing the GEC-ESTRO guidelines for contouring and prescribing dose to the high-risk CTV and contouring and calculating dose to organs at risk (OARs) including the rectum, bladder, and sigmoid colon (11). This approach was utilized at the Kathmandu Cancer Center in Kathmandu, Nepal where an HDR unit was donated by Radiating Hope in 2019. The first T&O treatments were in May of 2019 and doses were prescribed to Point A. Over 200 implants were done in a 6-month period until, with additional training, the physicians began image-guided brachytherapy in November of 2019. Any program transitions require careful follow-up to ensure efficacy and toxicity are acceptable.

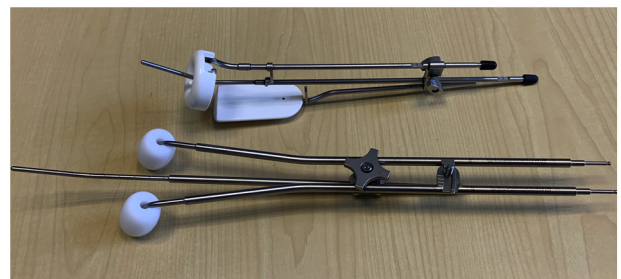


Fig. 2. Example of a tandem and ovoid applicator (front) and tandem and ring applicator (back).

### *Interstitial and hybrid implants*

Interstitial and hybrid implants offer the most flexibility and best dosimetry; however, they are also the most technically challenging and labor intensive. The hybrid implant can be used as a transition from applicator based implants to full interstitial. Often, the T&O or T&R implant can be supplemented with several needles that can improved dosimetric coverage of the target while decreasing dose to OARs. This technique can allow users to gain more experience with needles before moving to a full interstitial implant.

### *Others*

Other types of brachytherapy, such as skin, prostate, breast, could be added as the program grows and gains experience depending on the resident patient population. Machine and equipment requirements for treatment sites are outlined in the following.

Key points on starting cases: Incremental steps to more complex procedures avoid potential anxiety, frustration, and errors. Plan the program for success from the start with procedures that are easy to implement and build confidence. Use dry runs and end-to-end tests during the commissioning process so the team may familiarize themselves with the procedure(s) and gain comfort and experience.

### *Machine and equipment selection*

One of the most important aspects in developing and setting up a new brachytherapy program is choosing the appropriate equipment. Imaging equipment is necessary for visualization of the implant as well as treatment planning. A treatment delivery machine (afterloader) is needed, similar to a linear accelerator in EBRT. It is necessary to have applicators compatible with the afterloader for the planned treatments. The clinic will need methods for applicator cleaning, disinfection, and sterilization. Proper delivery of high-quality brachytherapy requires a commissioned treatment planning system and equipment.

As pointed out previously, brachytherapy requires a multidisciplinary treatment team that includes physicians, physicists, nurses, therapists, and dosimetrists (depending on resources and staffing models). Therefore, machine and equipment selection for brachytherapy should be a collaborative team effort to ensure that all needed items and their functionality have been evaluated carefully in terms of cost, physical space requirements, clinical applicability, compatibility with any existing technology (hardware and/or software), any history of reported medical events associated with hardware/software components, and any limitations including dependability, cleaning and reusability or end-of-life standards. In addition, equipment should be appropriate for the patients and procedures identified in the feasibility assessment of program development with adequate education available for proper use.

The equipment selection section can be further subdivided into five categories: imaging, treatment devices, treatment planning, applicators, and calibration/QA.

### *Imaging*

*Gynecological brachytherapy.* GYN procedures can use a variety of imaging devices: portable x-ray, computed tomography (CT), ultrasound (US), and magnetic resonance imaging. Some of these devices can be used during insertion such as transrectal or transabdominal US to ensure accurate placement of the applicator and prevent any undesirable outcome such as perforation or incorrect applicator depth, location, and orientation, whereas others are used after implant for dosimetry calculations like CT. However, using US requires experience and expertise in both using the modality and interpreting the imaging. In general, this does not require a radiologist to be involved but rather comes from the acquisition of this experience during training. There have been many publications regarding transition from 2D to 3D brachytherapy for GYN implants as there are many advantages to CT imaging for GYN procedures with reconstruction of applicators, use of applicator libraries, and 3D visualization of the target(s) and OARs with DVH metrics (11–14).

*Prostate brachytherapy.* For HDR procedures, it is a necessity to have a US unit with a transrectal probe that can provide an enhanced contrast/resolution throughout the image and all the anatomical details to perform a safe and accurate implant. This unit is used for target volume acquisition and applicator insertion. Again, it is generally not necessary to have a radiologist involved to interpret the imaging as it is relatively straightforward to learn. A biplanar unit with variable frequency probes that provide good flexibility for the user is essential. In addition, a reliable stabilization system is very important in providing a secure setup for the probe. A CT scanner is required for HDR needle position verification and treatment planning, when not using a US-based intra-op technique.

*Breast brachytherapy.* Fluoroscopy, US, and CT are typical imaging modalities used for breast brachytherapy. These can be used for accelerated partial breast irradiation procedures (balloon-based devices, strut-based devices, and interstitial implants). Images taken are used for applicator insertion, verification of its location and integrity before each treatment, and treatment planning.

### *Treatment devices*

HDR afterloaders are versatile because they are able to treat many types of cancer with use of the appropriate applicator. The most common isotope used is Ir-192, which has a half-life of approximately 74 days, and most sources come at an activity of about 10 Ci. In limited resource settings, it is important to consider replenishing the

radioisotope in the afterloader as treatment time increases with a decaying source. Treatment time with a source that has decayed to about 1 Ci could be over 1 h in duration. Some vendors offer Co-60 as an alternative to Ir-192 because of its long half-life (~5 years) and it might be a suitable alternative to Ir-192 for a clinic if it is impractical to ship, receive, and install a new source on a frequent basis.

#### *Treatment planning*

Most brachytherapy procedures utilize treatment planning software to generate a therapeutic dose to the target while minimizing dose to OARs. Some procedures still rely on the use of tables and nomograms, as it is the case for conical skin treatment, where treatment planning is not yet available. However, as most treatments transition to 3D imaging with CT, computer-based planning is necessary and it offers some advantages such as applicator reconstruction through the use of a built-in applicator library that allows a user to “snap an applicator into place” quickly and without risk of manual digitization errors.

#### *Applicators*

A variety of applicators can be used in brachytherapy. Common applicators for HDR interstitial implants are stainless steel, plastic, or titanium needles. GYN procedures are performed using a variety of shielded and unshielded applicators including cylinders, T&Os, T&Rs, tandem and cylinders, hybrid applicators, and interstitial needles.

Considerations for limited resource settings are the number of applicators necessary to treat the expected patient volume while considering the availability of cleaning and sterilization for reuse of an applicator. It may be necessary to consider buying sterilization equipment if none is available. It is also necessary to consider the lifetime of the applicators and if applicators become broken or destroyed, if the program can either continue treatments without an applicator or afford to replace it, or if it will not be sustainable in the long run.

#### *Commissioning, calibration, and quality assurance*

Before the implementation of a new brachytherapy program, or using a new device, applicator, or software, commissioning is essential to ensure safe introduction into the clinic. While most publications regard commissioning as key to safe implementation, many are nondescript in their approach, and some offer more prescriptive processes (15). Every center performs commissioning after acceptance of a new treatment device, so there is ample knowledge on how to perform this task. Many vendors can connect users that have experience and have previously commissioned equipment as they might be willing to share their experience and reports. This can be a good option for centers with little experience in a particular area.

Most regulations require that all radiation sources used, such as Ir-192, Co-60, must be verified (air kerma strength, activity, dose rate, etc.) before use in the clinic as well as periodic spot checks. A calibrated electrometer, well chamber, ionization chamber suited for the energy, thermometer, barometer, solid water phantom, 1D water tank, and film dosimetry (densitometer and software) are the most common equipment needed to perform these tasks. Commissioning of the treatment planning software is required before its use and can be verified after each upgrade using a variety of standard cases that have been previously planned and saved.

Key points on machine and equipment selection: It is paramount to select the correct equipment for the clinic and patient population to maintain a successful program. Because brachytherapy has recurring costs associated with source and applicator replacement, careful consideration should be taken on funding for these items. Overly costly or complex equipment, especially if rarely used, should be avoided if there is not adequate funding to repair or replace broken equipment or if lack of training and expertise could lead to improper use.

#### *Quality and safety*

A key component to the development and implementation of any new program is the foundation of a robust quality and safety plan. A minimum requirement, usually set by most regulatory agencies, requires a radiation safety program to be established before licensing for any type of radioactive isotope usage. However, this program is often generic, or nonspecific in many facets, and may include a bare minimum set of tests for a clinic to perform to maintain compliance. Programs should view literature from organizations such as the IAEA and AAPM for guidance on good practice (9,16).

In the United States, the Nuclear Regulatory Commission Regulations (10CFR35) state that an application for a license for medical use of byproduct material is required to have a radiation safety program as well as specific information on radiation safety precautions and instructions (17). Similarly, the IAEA has published Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards that states “principal parties shall establish and implement a protection and safety programme” (18). Licensing regulations will be dependent on local and national regulations. One of the challenges for developing countries could be working with the government to establish a program, especially if it is the first program in the country. If the program is not the first in the country, then communication to other clinics with programs and site visits may help in gathering information. If it is the first program in the country, then the IAEA is a good resource with both reference materials and personnel that can help assist a clinic. Alternatively, vendors often have regulatory

affairs personnel who can assist with regulatory compliance and interfacing with the government.

In the past decade, there have been a number of high-profile articles highlighting errors during medical application of radiation (19). There are multiple publications available on the internet outlining best practices with links to those articles on both the American Society for Therapeutic Radiation Oncology (ASTRO) and American Brachytherapy Society websites (20). There are a wide variety of reasons to explain the ongoing occurrence of these errors. Some causes include increased complexity of advancing technology, poor teamwork or communication, staff fatigue, compressed time frames and stress, or too much reliance on computer technology. However, another major cause is lack of proper education and training. The International Commission on Radiological Protection published Report 86 on Prevention of Accidents to Patients Undergoing Radiation Therapy in 2000 and then Publication 112 in 2009 entitled Preventing Accidental Exposures from New External Beam Radiation Therapy Technologies (21,22). In both publications, it states that “purchasing new equipment without a concomitant effort on education and training and on a program of quality assurance is dangerous”. Proper training for a new program is key to its success. Training for physicians in the United States is accredited by the Accreditation Council for Graduate Medical Education and involves a 48-month residency program that requires, at a minimum, the physician to perform seven interstitial brachytherapy cases and 15 intracavitary cases of which 5 must be uterine tandem-based insertions (23). Certification in the United States is through the American Board of Radiology that requires graduation from a program that is Accreditation Council for Graduate Medical Education accredited, thus ensuring some experience in brachytherapy implants. It should be noted that this is a minimum requirement and proficiency often requires additional experience. Typically, a health care system that hires the physician may require a period of preceptorship for the first 5–10 cases performed after residency. However, in the absence of a residency program, it can be challenging to obtain this experience especially in limited resource settings. Many organizations, such as the IAEA, AAPM, ASTRO, ESTRO, and Radiating Hope offer live training programs, whereas there are many other organizations that have begun to offer online distance education, such as Rayos Contra Cancer (<https://www.rayoscontracancer.org/>), and vendors offer user training on new equipment. Although all these programs are a great educational opportunity, they are often limited and cannot fully encompass all aspects of starting a brand-new program. In addition, many of these programs are offered in a small variety of languages, despite it being preferential to have a highly technical education program in one’s native language. Site visits to other centers performing treatments similar to those that will be implemented are a valuable opportunity and should be used when possible. When planning and

developing a new program, it is important to research education and training options and whether they will be adequate for safe implementation and sustainability of a program.

Another aspect of education is competency assessment. There can be a difference between attending a training course, learning concepts, and then attempting to apply those concepts in practice. In 2008, the World Health Organization published a technical manual on Radiotherapy Risk Profile (24). In this report, it was stated that competency assessment is one of the top three interventions that is likely to be an effective safety barrier. Competency assessment can take many forms such as quizzes, supervised observation of tasks or supervised observation of dry runs. These are highly effective and should be part of the ongoing training and education plan for implementing a new program. Not only are these useful for training new staff or adjusting to changes in a program, but they are beneficial in keeping staff familiar with a procedure, especially if it is performed with a low frequency.

Peer review is another critical component of the quality and safety program for any center. There have been a number of publications and recommendation regarding peer review including those by the American College of Radiology and ASTRO and AAPM (25–28). Peer review can allow for the discovery of inaccuracies that may often go overlooked without a formal review process. This is especially true in small centers with single physician or single physicist staffing. Challenges in limited resource settings might be lack of in-house expertise to establish a robust internal program or even recruiting peers for the peer review process; however, with more resources becoming available online, such as web-based programs, such as Chartrounds, or just email dialog with colleagues and experts internationally, or through societies such as the American Brachytherapy Society or GEC-ESTRO, it may be easier for centers to find others that can participate in online, remote reviews (29). External audits are another form of peer review that can add value through external validation of the treatment delivery process. Every effort should be made to collect data from all patients to track outcomes and analyze this information for evaluation of efficacy of a program.

The quality management plan for a new program should follow all local and governmental regulations as well as implement standards published in guidance documents from organizations and societies. Although preparation for the safest brachytherapy practice is paramount, errors or complications may still happen. Medical complications during or shortly after brachytherapy can occur including acute bleeding, oversedation, reactions to medications, visceral perforation, and infection. The brachytherapy team should consider instituting protocols and policies to manage these before starting a program. If a radiation delivery error occurs, disclosure and mitigation of risk to the patient is necessary. Error evaluation should commence

expeditiously and necessitates an honest, nonjudgmental evaluation of the factors that lead to the error so that safeguards can be put in place to prevent future errors.

Key points on quality and safety: As Hulick and Ascoli stated in their article “Quality Assurance in Radiation Oncology”, “quality assurance (QA) means being certain that things are done right” (30). It is a very simple, yet eloquent statement. When developing a program, it is essential to formulate a comprehensive education and training plan that will ensure competency before treatment of the first patient while also ensuring continuous education and ongoing competency evaluations. In addition, peer review should be implemented as part of the overall quality and safety program.

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