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Realizing Ultimate Patient Safety in Radiation Therapy using Transmission Detectors

A comparison could be drawn between radiation therapy and black magic - the patient doesn't see it or feel it, but must have faith in its ability to cure cancer. Every patient that is placed under the radiation beam trusts that it is safe, and it is the responsibility of manufacturers of the technology along with the clinical team to ensure that this trust is not broken.

If a $4 million high tech linear accelerator can't cure cancer, what else can? That said, it must be accurate and safe. If this assumption seems flawed, keep reading.

"The assumption is that if the choice is good, more choice is better. That's not necessarily true."
Barry Schwartz

Patient Safety: is it a good choice to assume?

Radiation therapy using photons produced by linear accelerators are the main work horse of the industry today. Delivery techniques have evolved over the last few decades – e.g. IMRT, VMAT, hybrid arc, SBRT and most recently hyperarc. Most often, a device developed for use has been used for a different technology. For example, the MLC that was developed to replace blocks has been used for IMRT delivery, and gantry technology developed for static movements has evolved for use in dynamic rotational therapy.

Good Choice Assumption: The LINAC has the tolerance set to trigger interlock when the parameters are out of tolerance. The dosimetry performance of the LINAC verified for patient treatment in a pretreatment is the same during treatment over the course of several days.

Patient Safety: is a "more good choice" assumption better?

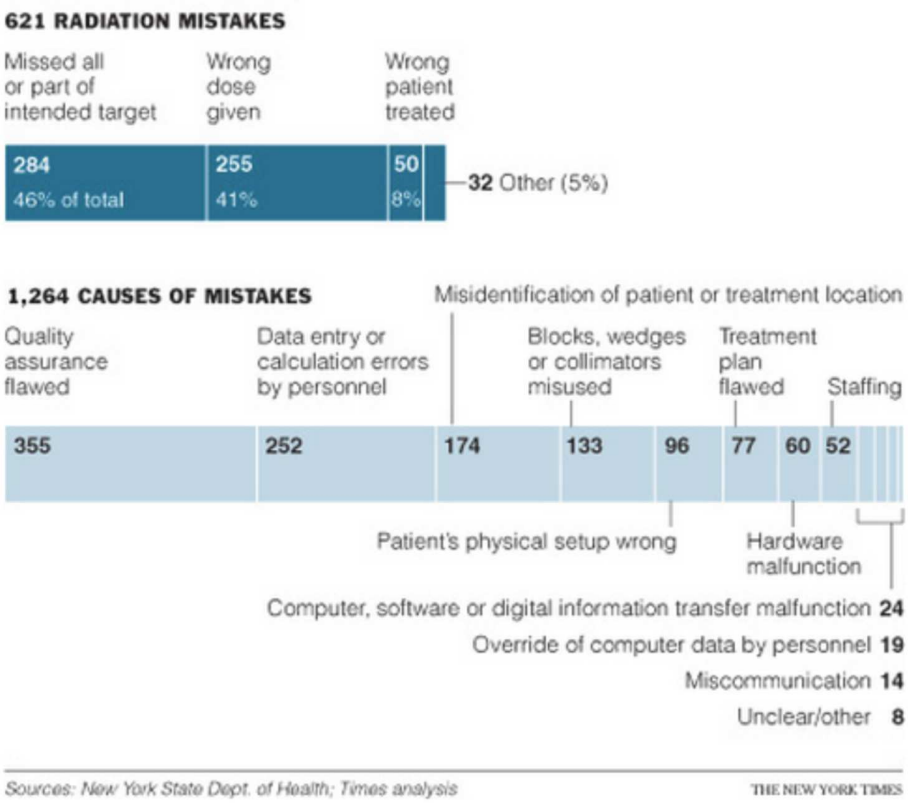
Due to the necessity to validate the patient treatment plan and the ability of the LINAC to deliver it with accuracy, there have been a plethora of tools available in the market to support validation, including film with an ion chamber, machine log file analysis, independent dose calculation, 2D array detectors and more.

More Good Choice Assumption: It has become clear that there is no single tool or method that can guarantee to catch all errors, and therefore multiple methods and safeguards have been clinically adopted and practiced to date. However, none of the tools that are commonly used can ensure the precise accuracy of the LINAC treatment delivery in real time, leaving us without clear records and documentation of the dosage delivered to the patient.

Patient Safety: the "good choice" assumption is not good enough, and potentially unsafe

Although we are aware that errors in radiation treatment are not adequately reported, data provided by the State of New York in the U.S., which has the most stringent regulations of medical device use in the nation, still indicates that 621 mistakes were reported between 2001 to 2009. On average, there are two contributing factors to these mistakes, as shown in the table below.

Although it is a good assumption that pretreatment QA and the machine interlock, in addition to a manual chart review, would be sufficient to ensure safety, consideration of the following example would indicate otherwise.



What is the barometer of safety?

In the United States of America, the legal system for medical malpractice is in place to ensure that patients are compensated in case of an unintentional error while receiving care. The system helps to ensure that the physician and clinical care team diligently deliver care. It is not clear whether the system actually helps to enhance safety or the quality of care, but it is clear that lawsuits are an ongoing concern for practicing physicians and hospitals.

Caveats in radiation therapy:

a) Identifying a radiation injury is difficult. Organ damage can take a long time to be detected and under-dosage is difficult to detect, as there is no injury.
b) Medical errors are not adequately reported.
c) Due to difficulty in identifying medical errors, most mistakes don't result in lawsuits. Reported medical malpractice claims are not thoroughly analyzed.

As such, we must serve as our own barometer. We should be able to document whether we have delivered the correct dose, under-dosage or over-dosage to our patients for each beam of radiation directed towards the cancer. Presently, as an industry, we don't document this due to a lack of proper technology. Until now.

According to a study in the International Journal of Radiation Oncology, Biology and Physics, the total cost of paid malpractice claims between 1985 and 2012 is $129,954,578 [1]. Table 1 shows the closed and paid claims over the last several decades. These claims may stem from a variety of causes, but the key takeaway is that hospitals and institutions need to make a conscious effort to promote safety, and more importantly, provide a credible perception of safety for their treatment. Table 2 shows where Radiation Oncology falls in comparison with other specialties in terms of malpractice risk.

Table 1: Malpractice claims in 1985-2012 in Radiation Oncology [1]

Close Year	Closed Claims*	Paid Claims†	% Paid of Closed Claims	Total Indemnity Paid††	Average Indemnity Paid††	Total Expenses - All Closed Claims††‖	Average Expenses - All Closed Claims††‖	Total Expenses - Paid Claims††‖	Average Expenses - Paid Claims††‖	Total Expenses - No Indemnity††‖	Average Expenses - No Indemnity††‖
1985	103	30	29.1%	$4,216,912	$140,564	$942,406	$9,150	$334,182	$11,139	$608,224	$8,332
1986	92	16	17.4%	$5,932,780	$370,799	$1,598,860	$17,379	$500,081	$31,255	$1,098,779	$14,458
1987	132	11	8.3%	$5,697,868	$517,988	$1,261,349	$9,556	$334,407	$30,401	$926,942	$7,661
1988	72	12	16.7%	$2,415,897	$201,325	$983,825	$13,664	$251,804	$20,984	$732,021	$12,200
1989	56	6	10.7%	$476,890	$79,482	$715,685	$12,780	$193,241	$32,207	$522,444	$10,449
1990	28	5	17.9%	$1,901,083	$380,217	$897,674	$32,060	$505,185	$101,037	$392,489	$17,065
1991	21	1	4.8%	$927,300	$927,300	$462,443	$22,021	$42,703	$42,703	$419,740	$20,987
1992	42	12	28.6%	$5,022,453	$418,538	$1,050,446	$25,011	$491,083	$40,924	$559,363	$18,645
1993	61	13	21.3%	$3,224,980	$248,075	$1,864,954	$30,573	$452,226	$34,787	$1,412,727	$29,432
1994	70	19	27.1%	$5,431,341	$285,860	$3,158,611	$45,123	$1,941,038	$102,160	$1,217,573	$23,874
1995	50	9	18.0%	$4,011,456	$445,717	$856,659	$17,133	$332,584	$36,954	$524,074	$12,782
1996	63	10	15.9%	$3,642,046	$364,205	$2,061,835	$32,728	$430,736	$43,074	$1,631,099	$30,775
1997	100	18	18.0%	$11,007,063	$611,504	$2,919,917	$29,199	$803,115	$44,618	$2,116,802	$25,815
1998	78	21	26.9%	$10,152,242	$483,440	$1,630,543	$20,904	$623,949	$29,712	$1,006,594	$17,660
1999	88	23	26.1%	$7,395,081	$321,525	$3,772,188	$42,866	$2,074,997	$90,217	$1,697,192	$26,111
2000	39	13	33.3%	$6,934,933	$533,456	$1,329,486	$34,089	$1,013,116	$77,932	$316,370	$12,168
2001	39	12	30.8%	$6,372,511	$531,043	$1,361,719	$34,916	$863,144	$71,929	$498,575	$18,466
2002	21	9	42.9%	$2,250,864	$250,096	$1,086,913	$51,758	$470,959	$52,329	$615,955	$51,330
2003	44	7	15.9%	$2,061,267	$294,467	$758,090	$17,229	$274,817	$39,260	$483,273	$13,061
2004	33	13	39.4%	$11,431,328	$879,333	$1,460,579	$44,260	$804,026	$61,848	$656,553	$32,828
2005	34	13	38.2%	$5,576,519	$428,963	$1,240,191	$36,476	$588,580	$45,275	$651,611	$31,029
2006	27	8	29.6%	$1,466,463	$183,308	$1,399,207	$51,822	$569,972	$71,246	$829,235	$43,644
2007	40	14	35.0%	$6,625,672	$473,262	$2,282,798	$57,070	$1,493,022	$106,644	$789,776	$30,376
2008	36	19	52.8%	$8,465,816	$445,569	$1,731,377	$48,094	$1,259,247	$66,276	$472,130	$27,772
2009	26	10	38.5%	$2,482,618	$248,262	$2,291,271	$88,126	$1,303,909	$130,391	$987,362	$61,710
2010	26	9	34.6%	$3,219,021	$357,669	$1,065,315	$40,974	$621,599	$69,067	$443,716	$26,101
2011	18	5	27.8%	$689,175	$137,835	$1,018,205	$56,567	$193,370	$38,674	$824,834	$63,449
2012	78	4	5.1%	$923,000	$230,750	$1,382,555	$17,725	$284,577	$71,144	$1,097,978	$14,838
Cumulative	1,517	342	22.5%	$129,954,578	$379,984	$42,585,100	$28,072	$19,051,669	$55,707	$23,533,432	$20,028

*Closed claims are medical liability claims that have been resolved through settlement or verdict or withdrawn, dropped or dismissed without payment.

†Paid Claims are medical liability claims that resulted in indemnity payment to the plaintiff as a result of settlement or court adjudication.

††Adjusted for inflation, 2012 index year[26].

‖Expenses are litigation expenses related to the defense of a liability claim, including expenses paid in the process of administering or adjudicating a claim.

Table 2: Closed Claims and indemnity payments by medical specialty, 1985-2012 [1]

Characteristics of closed claims and indemnity payments by medical specialty, 1985–2012

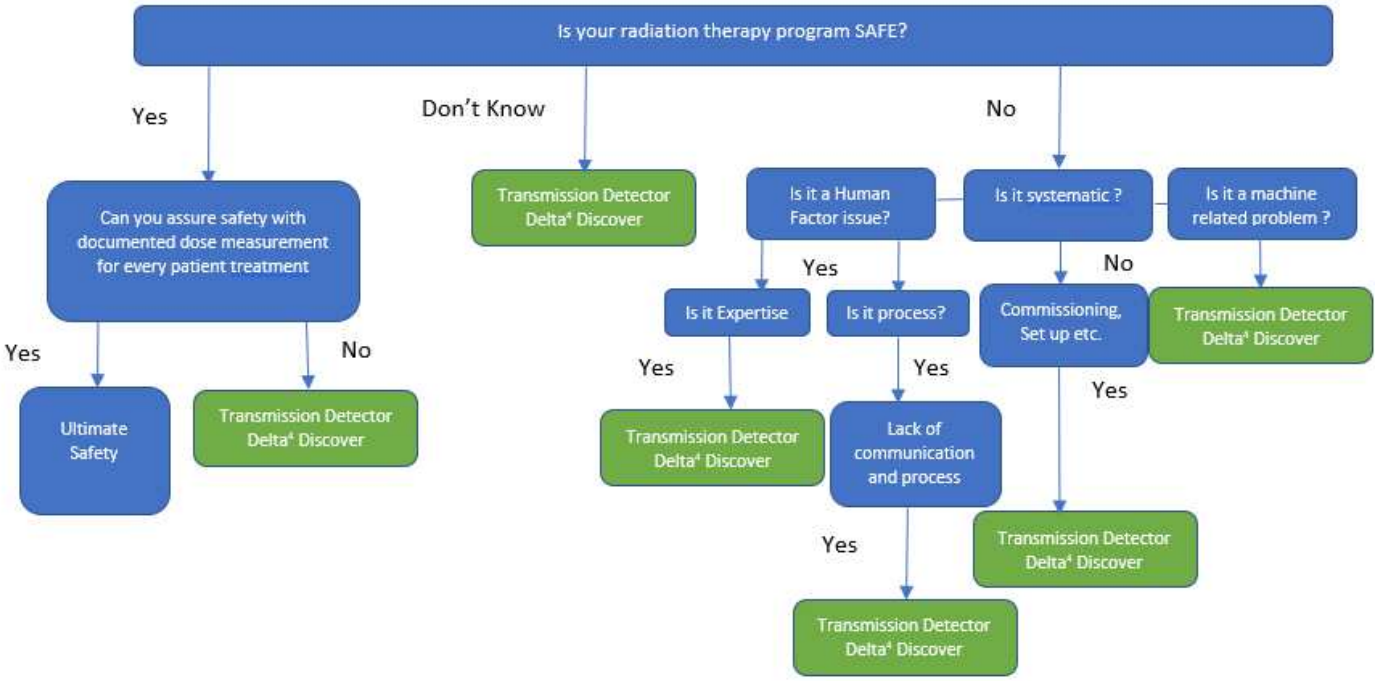
	Cumulative Closed Claims						
Medical Specialty	**Closed Claims***	**Paid Claims†**	**% Paid of Closed Claims††**	**Total Indemnity Payment‖**	**Average Indemnity Payment¶**	**Median Indemnity Payment**	**Largest Indemnity Payment**
Anesthesiology	11,030	3,470	31.5%	$856,516,675	$246,835	$96,774	$5,048,678
Cardiology	5,371	1,032	19.2%	$271,207,784	$262,798	$156,250	$2,000,000
Cardiothoracic Surgery	7,948	1,900	23.9%	$457,058,679	$240,557	$125,000	$5,005,000
Dermatology	3,198	906	28.3%	$130,900,558	$144,482	$35,000	$3,000,000
Emergency Medicine	6,887	1,864	27.1%	$461,440,009	$247,554	$120,000	$2,000,000
Gastroenterology	3,521	661	18.8%	$170,353,285	$257,721	$119,559	$4,000,000
General and Family Practice	30,453	9,639	31.7%	$1,703,213,764	$176,700	$82,246	$7,239,248
General Surgery	29,400	9,822	33.4%	$1,978,471,304	$201,433	$99,999	$3,116,180
Internal Medicine	37,216	9,271	24.9%	$2,106,112,462	$227,172	$101,400	$12,000,000
Neurology	4,474	979	21.9%	$326,529,544	$333,534	$175,000	$5,000,000
Neurosurgery	6,443	1,814	28.2%	$599,483,751	$330,476	$183,735	$5,600,000
Obstetrics and Gynecology	40,266	13,761	34.2%	$3,959,561,785	$286,324	$149,250	$13,000,000
Ophthalmology	7,893	2,232	28.3%	$429,207,088	$192,297	$100,000	$3,550,000
Orthopedic Surgery	25,707	7,404	28.8%	$1,329,643,166	$179,584	$90,000	$3,000,000
Otorhinolaryngology	4,627	1,529	33.1%	$336,006,438	$219,756	$100,000	$4,199,329
Pathology	1,991	594	29.8%	$158,426,561	$266,711	$137,500	$2,700,000
Pediatrics	7,825	2,180	27.9%	$618,020,900	$283,496	$126,251	$5,250,000
Plastic Surgery	10,174	2,697	26.5%	$333,545,019	$123,673	$50,000	$2,000,000
Psychiatry	2,666	526	19.7%	$84,278,265	$160,225	$55,000	$2,375,000
Radiation Oncology	**1,517**	**342**	**22.5%**	**$94,662,971**	**$276,792**	**$122,500**	**$2,700,000**
Radiology	16,411	4,740	28.9%	$1,088,473,008	$229,636	$100,000	$3,364,156
Urologic Surgery	7,099	2,009	28.3%	$402,586,508	$200,391	$100,000	$3,200,000
All specialties	272,117	79,372	29.2%	$17,895,699,524	$225,221	$100,000	$13,000,000

*Closed claims are medical liability claims that have been resolved through settlement or verdict or withdrawn, dropped or dismissed without payment.

†Paid Claims are medical liability claims that resulted in indemnity payment to the plaintiff as a result of settlement or court adjudication.

Realizing Ultimate Patient Safety: Eliminating assumptions and embracing assurance

Safety cannot be assumed, it must be assured. Transmission detectors provide a technology that ensures (and documents) that the correct dosage is delivered by the LINAC for every beam, every fraction and every patient. The Delta^4 Discover system from ScandiDos is the first commercially available FDA approved transmission detector that allows cancer treatment clinics around the world to realize ultimate patient safety.



Provider Peace of Mind: Transmission detector technology provides ultimate safety when all other steps in the process fail to identify a treatment deviation or unknown delivery error, which is currently measured and analyzed.

Patient Peace of Mind: Perception is reality. Regardless of how effective the treatment might be, patient peace of mind is of paramount importance to their psychological health. There is no other advanced QA technology other than the use of a transmission detector in radiation therapy delivery. Making this state-of-the-art technology available to our patients is vitally important for all safety- and quality-centric programs.

Safety is an investment, not a cost

A safety- and quality-driven organization will utilize the latest technology in patient safety, and transmission detectors play a key role in this field. Documenting the delivery quality for every fraction, beam and control point is an important step towards increasing patient safety throughout the treatment process. We must continue to pursue the latest advancements in QA and develop our programs to include the most current technology whenever possible. With the Delta^4 Discover transmission detector, we can now realize ultimate patient safety while providing peace of mind to providers and patients.

The Delta^4 Discover: Ultimate Patient Safety Technology

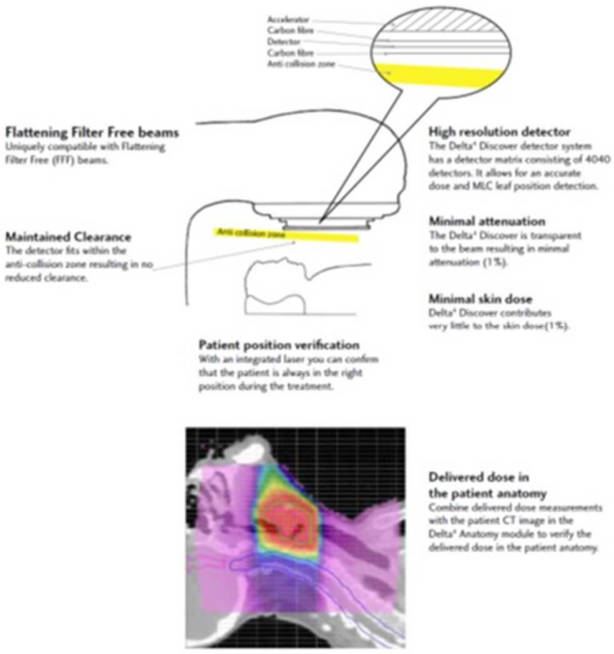
What is the Delta^4 Discover?

The Delta^4 Discover in an ultra-thin transmission detector. The technology provides verification of accurate dose delivery at treatment, in the patient's anatomy and for every treatment fraction. Thus, you can be assured that your patients are

receiving their treatment according to the dose prescription and that you are avoiding errors in the dose in critical structures.

How does the Delta^4 Discover work?

The Delta^4 Discover system measures the dose that is delivered by the accelerator and automatically checks it against pass-fail criteria to ensure that the treatment is precisely delivered according to the plan. In conjunction with the patient CT, you are able to verify the dose that has been delivered to the patient.



What are the implications for the patient and your clinic?

Peace of mind. True safety is ensured and documented. Both you and your patient can now be confident that the dose is delivered precisely as it was planned. Also, you have access to dose documentation for the treatment, which is an ultimate testament to quality and safety assurance for our patients.

Reference

1. Medical malpractice claims in radiation oncology: a population-based study 1985–2012, Deborah C. Marshalla, Rinaa S. Pungliab, Dov Foxc, Abram Rechtb, and Jona A. Hattangadi-Gluth, Int J Radiat Oncol Biol Phys. 2015 October 1; 93(2): 241–250. doi:10.1016/j.ijrobp.2015.05.040