

Realizing Ultimate Patient Safety in Radiation therapy using Transmission detectors

Radiation therapy is like black magic, patient don't see it, feel it but must believe it cures cancer. Every patient that we put under the radiation beam trust that it is safe. It is the responsibility of the vendors and the clinical team that trust is not broken.

If a 4 Million Dollar high tech linear accelerator cannot cure cancer what else can? It got to be accurate and safe. If you don't believe in this assumption read ahead.

“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 main work horse of the industry. Radiation therapy delivery techniques have evolved over the last couple of decades. For example, IMRT, VMAT, hybrid arc, SBRT and most recently hyperarc etc. Most often the device developed for a use has been used for a different technology e.g. MLC developed to replace blocks has been used for IMRT delivery, gantry technology developed for static movements have evolved to use for dynamic rotational therapy.

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

Patient Safety: Is More Good Choice assumption is better

Since because of the necessity to valid the patient treatment plan and the ability of the LINAC to deliver accurately there has been plethora of tools available in the market all the way from film with ion chamber, machine log file analysis, independent dose calculation, 2D array detectors etc.

More Good Choice assumption: It has been very clear that there is not one tool or method that guarantee to catch all the errors so there are multiple methods has been clinically adopted and practiced to date. None the tools that are currently adopted ensure what is happening in real-time to the LINAC treatment delivery leaving us with no record of what was delivered to the patient.

Patient Safety: Why good choice assumption is not good enough or potentially unsafe:

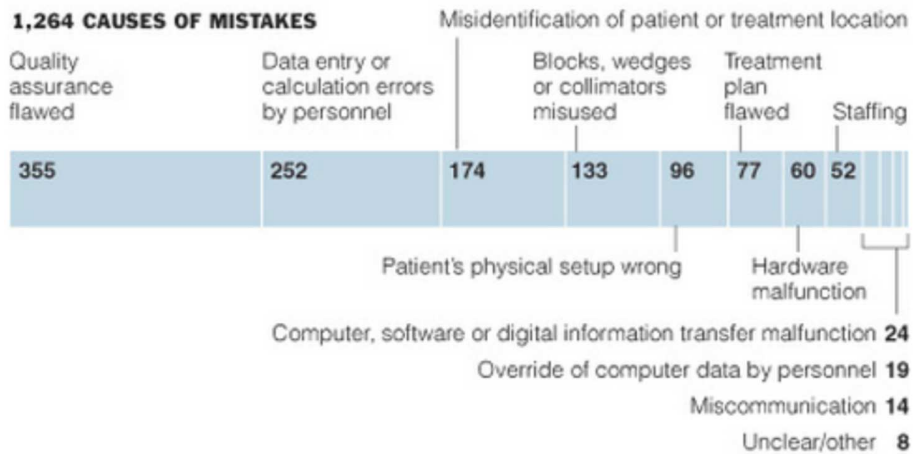
While we know, the errors are not adequately reported, just looking at New York State, USA the most stringent regulator of medical device use in the nation, 621 mistakes were reported between 2001 to 2009. On average, there were two contributing factors which the below table shows.

So, though it is a good assumption that pretreatment QA and the machine interlock along with manual chart review would enough to assure safety, that is not the case reviewing this one examples.

621 RADIATION MISTAKES



1,264 CAUSES OF MISTAKES



Sources: New York State Dept. of Health; Times analysis

THE NEW YORK TIMES

What is the barometer of safety in any field? Medical Lawsuit

In USA, medical malpractice system is in place to ensure that the patients are compensated in case an unintentional error happens while providing care. This is also to ensure that the Physician and the clinical care team perform the care diligently. It is not clear that whether this system is helping in enhancing safety or quality of the care but it is clear that being sued is always a concern for practicing physicians and hospitals.

Caveats in our Radiation therapy

- a) Identifying radiation injury is difficult. Organ damage can take 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) Because of difficulty in identifying medical errors, most mistake doesn't result in lawsuits. The reported medical malpractice claims are not elaborately studied.

We need to be our own barometer. We should be able to document whether we have given correct, under or overdose to our patients for each beam of radiation directed towards the cancer. Currently as an industry we don't do that because of lack of technology to do that until now.

According to a study in International Journal of Radiation Oncology, Biology and Physics, the total cost of the paid malpractice claims between 1985 and 2012 is USD 129,954,578[1]. Table 1 shows the closed and the paid claims over the last couple of decade. These claims may be caused because of several reasons but this shows that hospitals and institution needs to make a conscious effort to promote safety and more importantly provide a credible perception of safety of their treatment. Table 2 shows where Radiation Oncology falls compare to 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 year²⁶.

††† 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 speciality, 1985-2012 [1]

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

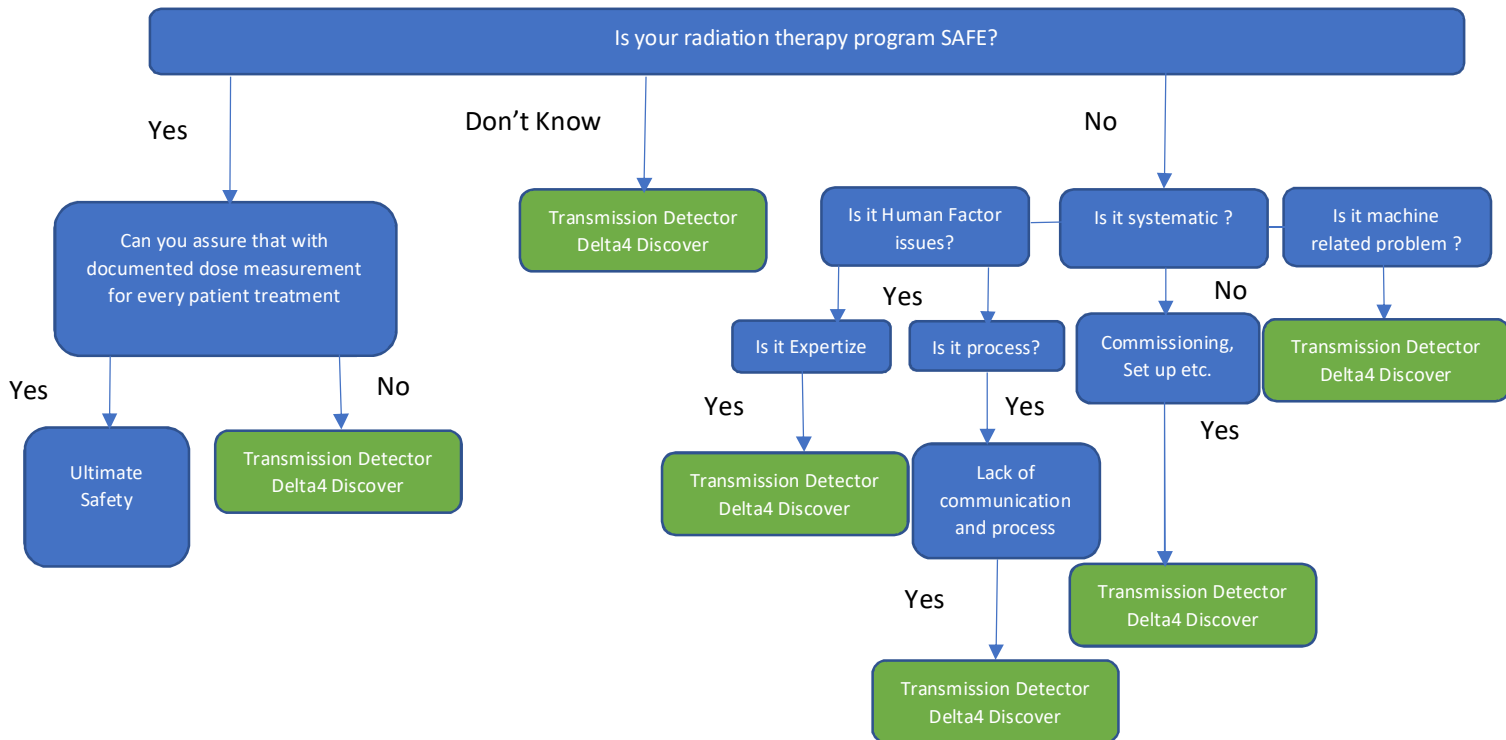
Medical Speciality	Cumulative Closed Claims						
	Closed Claims [*]	Paid Claims [†]	% Paid of Closed Claims ^{††}	Total Indemnity Payment ^{†††}	Average Indemnity Payment ^{†††}	Median Indemnity Payment	Largest Indemnity Payment
Anesthesiology	11,030	3,470	31.5%	\$856,516,675	\$246,835	\$96,774	\$5,048,678
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 assumption and embracing Assurance

Safety cannot be assumed, it must be assured. Transmission detector is one such technology that ensure, documents and assures correct dose is delivered by the LINAC for every beam, every fraction and for every patient. Delta4 Discover from ScandiDos is the first FDA approved transmission detector that is commercially available to facilitate clinic around the world to realize ultimate patient safety.



Provider Peace of mind: A technology such as transmission detector provides ultimate safety when all other process steps fail to catch the treatment deviation or unknown delivery error which is currently more measures & analyzed.

Patient Peace of Mind: Perception is reality. However, the great treatment might be patient peace of mind about their care is very critical for their psychological health. There is no other advanced QA technology than transmission detector in radiation therapy delivery. Making that available to our patient is important for all safety and quality centric programs.

Summary: Safety is an Investment -not a cost!

A highly reliable 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 a 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 most current technology whenever possible. With the Delta4 Discover transmission detector, now we can realize ultimate patient safety along with providing peace of mind to providers & patients.

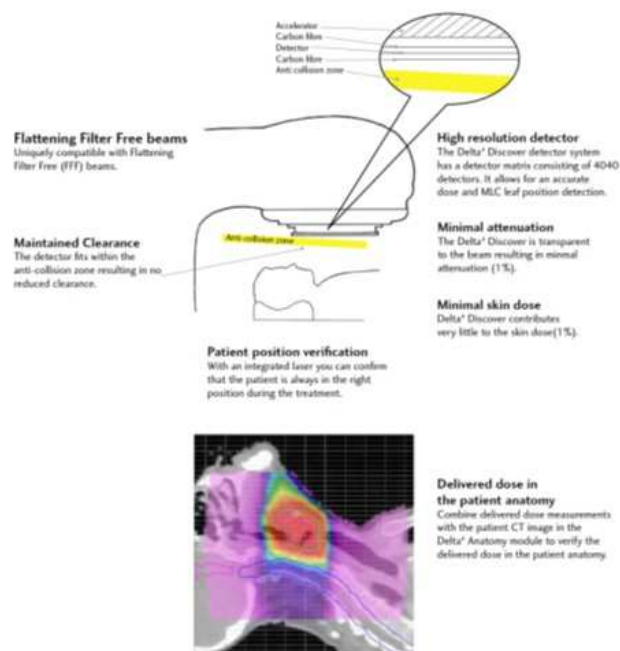
On Delta4 Discover: Ultimate Patient Safety technology

What is Delta 4 Discover?

Delta4 Discover is an Ultra-thin transmission detector. The Delta4 Discover technology allows accurate dose delivery verification at treatment, in the patient anatomy and for every treatment fraction. Thus, you can be ensured that your patients are treated according to the dose prescription and avoid errors in the dose in critical structures.

How does Delta4 Discover work?

The Delta4 Discover system measures the dose that is delivered by the accelerator and automatically checks against pass-fail criteria that the treatment is done according to the plan. Together with the patient CT you can see the dose that has been delivered to the patient.



What does it mean to the patient and the program?

Peace of mind. Safety assured and documented. Both you and your patient can now be confident that the dose is delivered as it was planned. Also, now you have dose documentation of what we have done to our cancer patients which is an ultimate testament of 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