Have Benchmarks and Pre-treatment Reviews Impacted the Clinical Trial Deviation Rate

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Purpose:

The mission of IROC Houston is to assure the NCI that participating institutions deliver prescribed radiation doses that are clinically comparable and consistent. This is accomplished through credentialing, and pre-treatment and retrospective reviews of submitted patient data. In 2016, IROC Houston began tracking the results of the aforementioned credentialing techniques to determine their impact on clinical trial deviation rates.

Methods:

In this study we looked at the deviation rates for benchmarks, pre-treatment, and retrospective reviews. Benchmarks are performed prior to enrolling a patient on study. Pre-treatments are completed prior to the start of a patient's treatment. Retrospective reviews are completed post treatment. All 3 types of reviews were performed using anonymized DICOM data and MIM software tools.

Results:

Over the past 18 years the major deviation rate has remained consistent for retrospective reviews, minor variations have increased and per protocol agreement has decreased (Figure 1). During the past 3 years, pre-treatment and benchmarks show a major deviation rate of 21% and 13%, respectively, and minor deviation rate of 23% and 33%, respectively (Table 1).
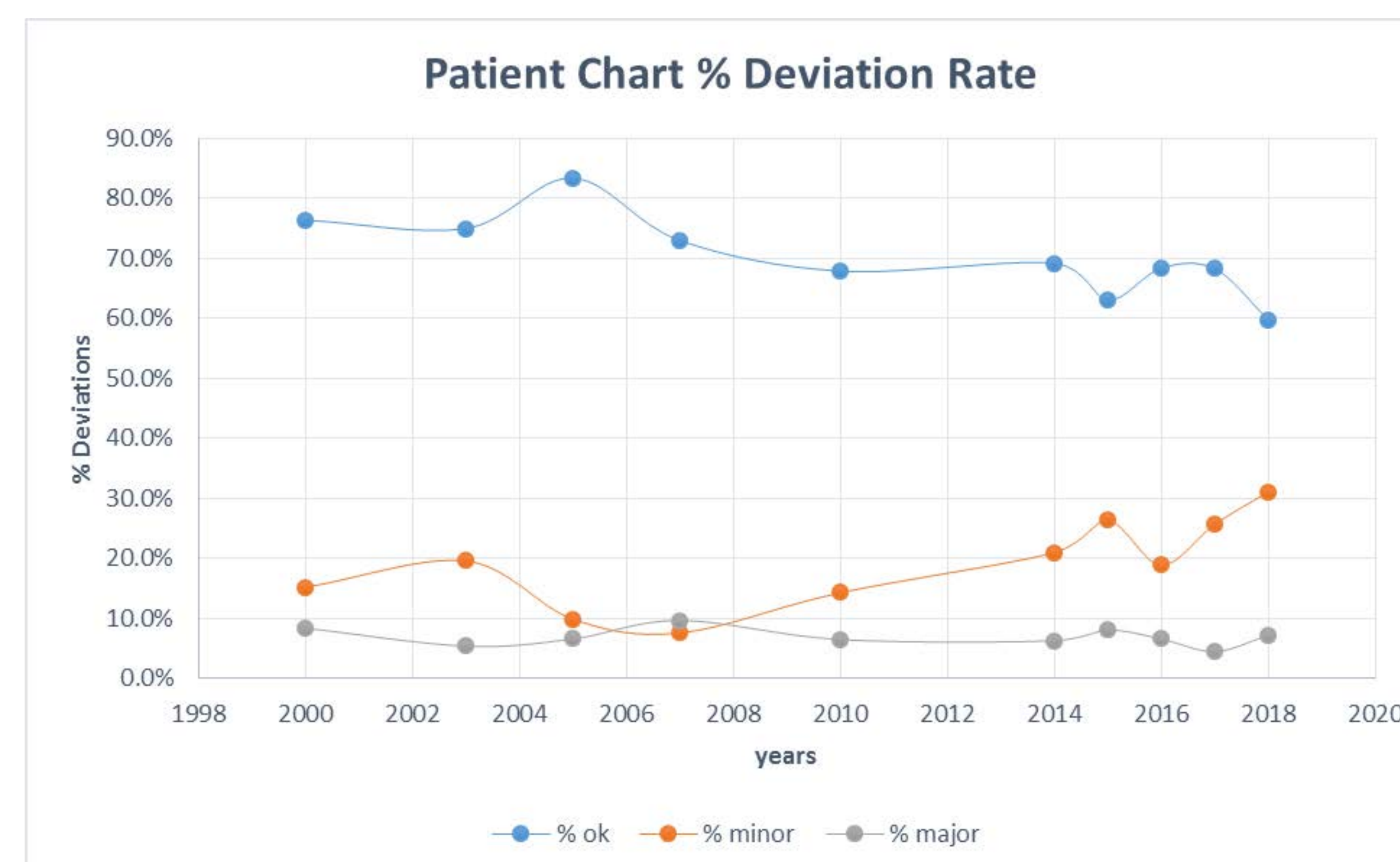

Figure 1: % Deviation Rate per year of major, minor and per protocol deviations

Deviation Rates Over Last 3 Years						
Year	2016		2017		2018	
Post-Treatment Reviews						
Total # of Charts	544		268		264	
OK	372	68.4%	183	68.3%	158	59.8%
Minor Deviation	103	18.9%	69	25.7%	82	31.1%
Major Deviation	36	6.6%	12	4.5%	19	7.2%
Tx Modification	33	6.1%	4	1.5%	5	1.9%
Pre-Treatment Reviews						
Total # of Charts	81		48		109	
OK	38	46.9%	26	54.2%	74	67.9%
Minor Deviation	26	32.1%	12	25.0%	12	11.0%
Major Deviation	17	21.0%	10	20.8%	23	21.1%
Benchmark Reviews						
Total # of Charts	266		129		152	
OK	103	38.7%	68	52.7%	104	68.4%
Minor Deviation	129	48.5%	45	34.9%	25	16.4%
Major Deviation	33	12.4%	16	12.4%	22	14.5%

Table 1: Deviation Rates from 2016 thru 2018 for post-treatment, pre-treatment and benchmark reviews.

Results (cont'd):

The decrease in deviation rates over the past 18 years is not unexpected since the purpose of the benchmark and the pre-treatment review is to educate and correct any errors made before a patient is actually treated on a protocol.

Conclusion:

Over the last two decades technology and delivery mechanisms have become more complex as have clinical trial protocols. Through the use of benchmarks and pre-treatment reviews, we have been able to educate institutions on how to contour and plan according to protocol specifications. Through this process we have been able to increase the rate at which institutions complied with the protocol, thereby affirming that the dose delivered to protocol patients are consistent with what the protocol intended to be delivered.

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