Design of Site-Specific Prognostic Morbidity-Mortality Studies and Internal Outcome Focus Studies in Radiation Oncology

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This research focuses on morbidity-mortality reviews and internal outcome focus studies. Definitions are provided as well as a complete discussion of the ideal parameters to consider when constructing each of these. The implementation of the design characteristics used may be of assistance to a center pursuing achievement of these requirements toward accreditation to exemplify continuous quality improvement in external-beam radiation therapy. The article further provides the educational tools necessary for readers to mature expanded studies from it for advanced site-specific clinical analyses.

Key Words: Accreditation, morbidity, mortality, outcome, rates

INTRODUCTION

In the process of radiation oncology department accreditation, surveyors pay close attention to continuous quality improvement in the clinical section. There are 7 primary areas of attention in this clinical continuous quality improvement process, each supervised and orchestrated by the medical director, and are separate from the technical and scientific areas supervised by the Chief Medical Physicist. These include chart review, individual physician peer review, patient satisfaction surveys, new patient conferences, port film and image review, morbidity and mortality review, and finally a focused review of internal outcomes. Most of these objectives are routinely conducted at centers across the nation. However, morbidity, and mortality and internal outcome studies typically seem to be either absent or not well assembled at many. This occurrence becomes increasingly valid for stand-alone facilities and for those that have not gained reporting benefits from an affiliated hospital's Cancer Registry Department.

This research focuses on these latter 2 primary objective areas: morbidity and mortality reviews and focused reviews of internal outcomes. Definitions are provided as well as a complete discussion of the ideal parameters to consider when constructing each of these. The implementation of design characteristics used may be of assistance to a center pursuing continuous quality improvement in external-beam radiation therapy, which is required for accreditation to be granted by ACRO or ACR-ASTRO. The article further provides the educational tools necessary for readers to mature expanded studies from it for advanced site-specific clinical analyses.
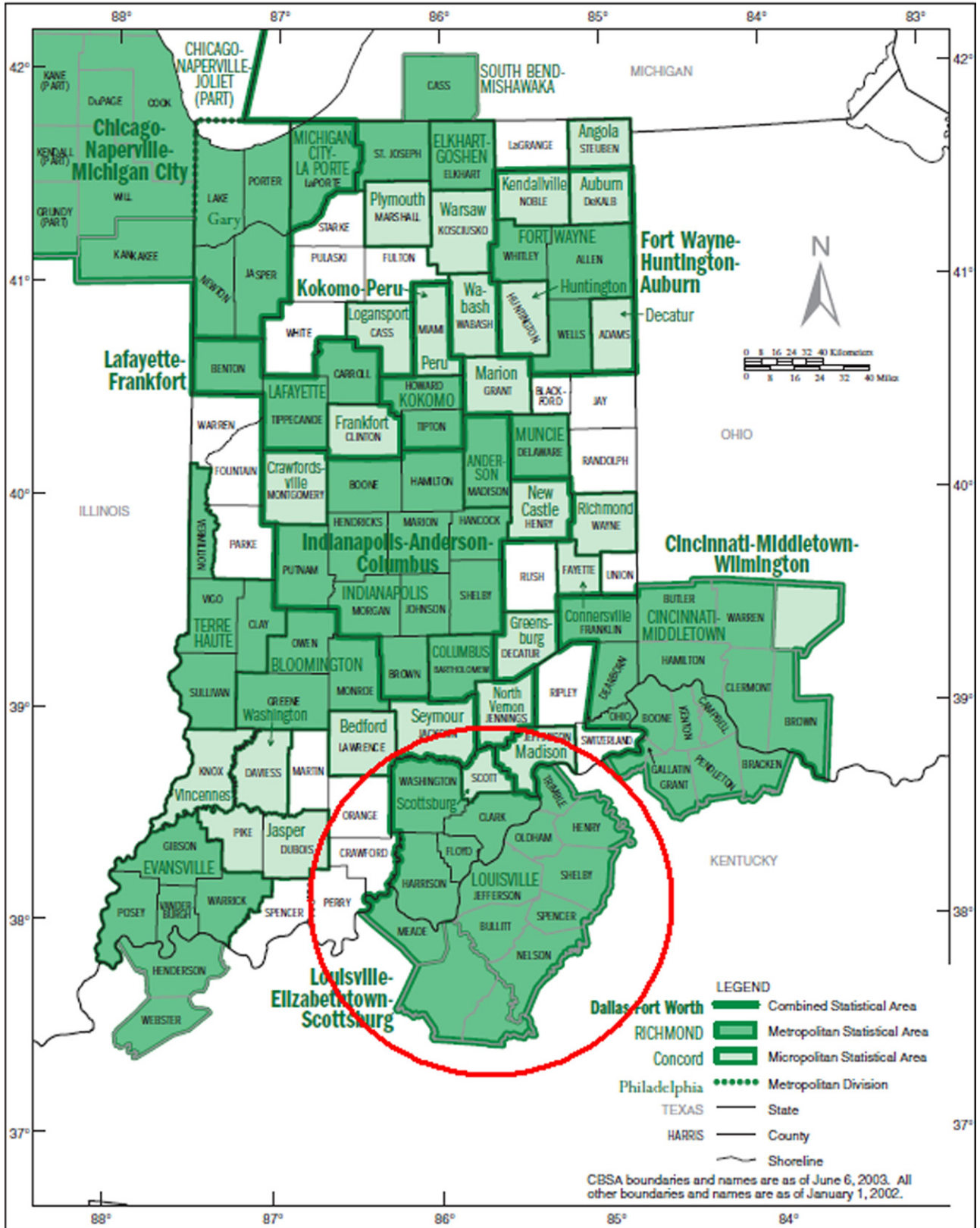
METHODS

Morbidity (change in rate) and mortality (change in count) are generally analyzed in terms of indices, on the basis of the population of a metropolitan area from which a cancer center draws patients. Since the index for each changes from year to year, a rise or fall is directly related to the number of clinical presentations, the prognostic aim for treatment, the life span of each patient, and other such factors. These changes may be used by radiation oncologists to recognize patterns in overall patient clinical performance, clinical treatment regimens prescribed, and the rate of incidence of cancer in their area. A census is necessary to monitor patterns of population change in the referral region, which is specifically defined as the population in the associated metropolitan area [1]. Consequently, when reviewing indices for changes in morbidity and mortality, the population difference with respect to a baseline year must be incorporated. The number of occurrences in each category is equivalent to the counted number of patients treated, multiplied by a baseline weighting factor and then divided by the metropolitan population. One can make use of a scaling factor of 100,000 to be multiplied in afterward to reduce the complexity of the mathematics, because most

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INDIANA - Core Based Statistical Areas and Counties

Fig 1. Metropolitan statistical area involving a facility in southern Indiana inclusive of the population in northern Kentucky.

metropolitan areas have populations on the order of hundreds of thousands. Rescaling the data changes the result to a population index, which is ideal for statistical tracking that is ongoing throughout the year and representative of results for each and every patient seen. The weighting value is determined from the first ever study conducted annually. It is found by dividing out the number of charts reviewed in that baseline year from the current yearly total number of charts reviewed. Although sampling of large sets of data does not provide the most precise results, it is the most time-efficient approach. Still, a valid census can be obtained and compared to prior years when the population variance is entirely removed. This is especially important for analyzing the morbidity-mortality index, because patient charts are typically sampled throughout the year at follow-up. For focus studies however, every patient chart is reviewed for tracking information at the time of chart closeout.

When dealing with morbidity-mortality indices, it is important to recognize which of 3 categories are being investigated explicitly. The survival morbidity-mortality index (SMMI) indicates cancer trends for increased patient death or life retention as a result of therapy at a center and within the community. It surveys only whether patients are alive or dead. The general morbidity-mortality index (GMMI) differentiates information between patients whose ultimate fates were alive or dead into further specific categories of curative or palliative intent. The prognostic morbidity-morbidity index (PMMI) sheds light on this information, but adds more complex details to indicate whether the disease is known, unknown or whether there were complications such as death occurring as a result of the presence of disease. An internal outcome focus study can be best described as an appendix of data for the PMMI. While separating data into the categories of curative and palliative intent, it indicates which specific site of treatment is common for completing treatment regimens. It details which patients of a certain cancer type complete treatment vs those found to be incomplete as a result of death or by decision of the patient, family, or physician to stop radiation therapy. These data are site specific, outcome specific, and tabulated with prognostic design. Each of the 3 indices as well as the internal outcome focus study is presented here.

The first step in obtaining data for any of these indices is to properly identify the metropolitan statistical area encompassing the center. Identification of the defined metropolitan area name is provided by the US Census Bureau and representative of all local affiliated counties in that region [1,2]. Metropolitan areas are interstate representative. Therefore, a metropolitan area may be associated with counties in multiple bordering states. Maps of these statistical area boundaries can also be obtained for additional referencing [3]. An example of one such metropolitan area is shown in Figure 1 for a cancer center receiving patients from 2 states.

Data used for some of the statistical analysis can be obtained by simply tracking results at the time of chart closeout. Since a final chart review should be conducted by a qualified medical physicist for every patient under treatment anyway, data tracking can be easily incorporated into the routine [4,5]. A spreadsheet with running totals provides the simplest construct. During a final chart review, the reviewer will need to first identify whether the intent was curative or palliative. Then, it must be determined whether the treatment was entirely completed, incomplete due to death, incomplete due to patient or family discretion, or incomplete due to a stop order from an attending physician. Finally, a mark can then be added to the spreadsheet that reflects each of these findings for a specific anatomic site of treatment to count that patient's occurrence.

Additional information is necessary to track the status of disease during that year from continual routine evaluations. This kind of chart follow-up requires sampling of data and cannot be solely conducted at closeout. As a result, a second person from the clerical area may be the ideal candidate to be assigned this task. For a busy center seeing more than 1,000 patients per year, it may be beneficial to review as many as 200 charts for a reasonable sample. Again, a spreadsheet will permit the best tracking mechanism for running these totals through the year. Usually, these are observed from physician consultations or follow-up reports. Along with the desired physician treatment intent being curative or palliative (or even prophylactic), it is the aim of the SMMI, GMMI, and PMMI to determine how these are further divided. Patient follow-up prognoses are categorized from the status of being determined still alive with cancer present, alive with cancer unknown, alive with no evidence of disease, dead due to disease, dead with cause unknown, dead with cause unrelated, or dead from complications.

As an example to illustrate the process, patients may be given external-beam radiation therapy to more than one site at a time. My experience with these types of studies suggests that occurrence rate computations are most easily performed with prescription-based data entry. If con-
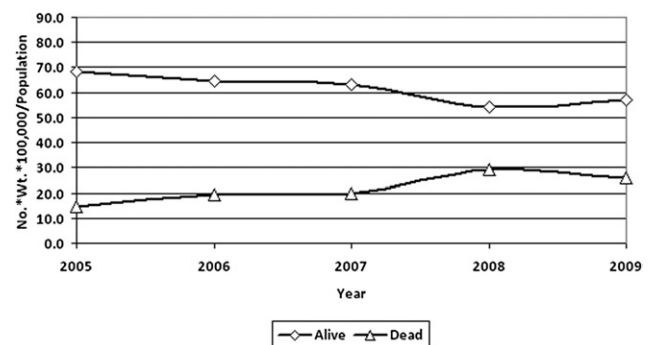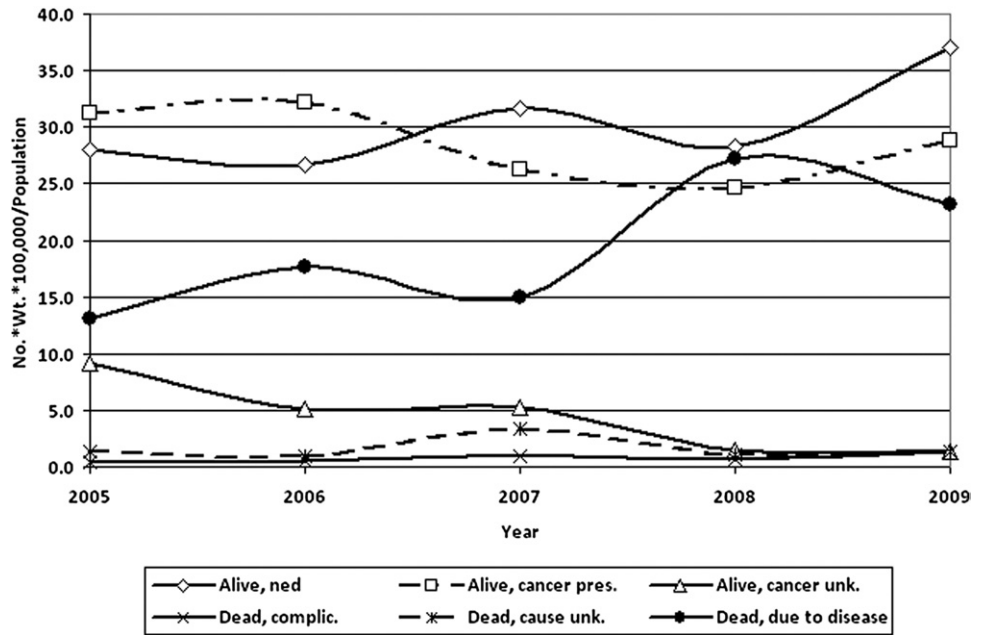

Fig 2. Artificial survival morbidity-mortality index plot over time.
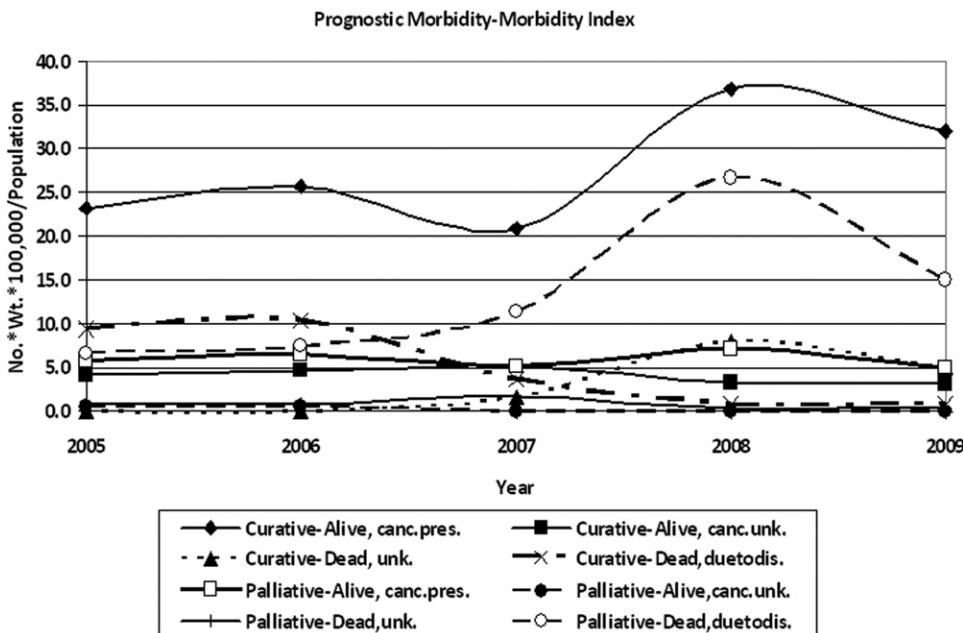
Fig 3. Artificial general morbidity-mortality index plot over time.

ducted without this separation of site-specific data, a patient's decision to decline further treatment can make for an undesirable question of where to assign the mark in the running total. A complicating example is as follows: a patient already under treatment for a lung cancer is close to completion when a metastatic tumor is identified in the brain. The patient then decides that after only having a few fractions of the newly started brain treatment, he wishes to discontinue it immediately after completing the entire lung prescription. During closeout, the medical physicist tracks palliative intent with completion for the lung but incomplete treatment due to patient decision for the brain

site. After reviewing end-of-year follow-up reports, a nurse then tracks the patient as still alive with cancer still present. In this example, had the data entry been based solely on the location of the primary tumor, the physician would then have gained no review benefit in the finding that the patient quit treatment.

In general, data entry for these type investigations is best conducted independently. If the anatomic location has a prescription specifically for it, then statistical tracking should be done for it separately. All of the statistical indices of interest can be derived from the data obtained during chart closeouts and follow-up review.

Fig 4. Artificial prognostic morbidity-mortality index plot over time.

RESULTS

The survival morbidity-mortality index indicates cancer survival progression and regression. This kind of life retention statistic is illustrated in Figure 2 on the basis of tracking data once radiation therapy was initiated and finishing at the end of that tracking year. In this plot, the population index for those patients documented as alive and continuing medical care has gone from decreasing since 2005 to increasing in 2009. Conversely, the number of patients who died after radiation therapy is decreasing in the most recent year. According to the level of the index, there are more patients alive than dead after treatment. As determined from the data provided, the baseline year is defined to be 2005. Again, this index is determined from follow-up data, throughout the year in question, and calculated by weighting the results in proportion to the total number of charts reviewed in the baseline year. For quality assurance on the statistical data, the curves should be mirror images of each other, as indicated here. The survival index is the most simple of the morbidity-mortality studies to produce.

The GMMI differentiates information between patients whose ultimate fates were alive or dead into further specific categories of curative or palliative intent. Figure 3 illustrates trending for various subcategories. Considerable differences are noted between the evaluation years (2008-2009) for a few categories detailed in the GMMI. Markedly, the greatest positive is the index representing the number of patients who are dead because of disease, which has declined by 5% from 28% occurrence to 23%. In parallel to that, more patients are also alive with cancer still present. This suggests that treatment regimens were beneficial in extending the life of patients. There is plausibility to this being partially attributed to the recent redevelopment in the radiology department, where better imaging capabilities were made possible in 2009. Also, there may have been additional staffing change benefits, with the introduction of more radiologists and urologists. Low indices remain for patients who are either alive or dead with unknown disease or who have died from complications. The low index suggests that these results happen infrequently (<5%) and that medical intervention has resulted in disease identification and successful treatment for more than 95% of patients. Still, it may be advantageous to review timelines for patient initial diagnosis, referrals, or specialized care consultation with expert physicians to the time when radiation therapy is prescribed. An overall general assessment to the status of successful cancer management in the community can be appreciated through this kind of analysis.

The PMMI expresses the same information stated above, but adds more complex details to indicate whether the disease is known or unknown or whether there were complications such as death occurring as a result of the presence of disease. An example of such a plot is shown in Figure 4. The PMMI divides up the GMMI in terms of

Table 1. Artificial internal outcome focus study raw data for 2009

	Brain	H/N	Breast	Lung/ Trachea	CW/Sclv Pab/IMC	Bladder	Ov/Uter/ Cerv/Endo	Shoulders	Prostate	Abd/ Esoph	Colon/ Rectum	Hips	Extremities/ Skin	Spine
Curative														
Complete	12	34	56	76	29	1	7	2	46	5	15	3	46	4
Incomplete (died)	0	1	0	2	0	0	1	0	0	0	0	0	0	1
Incomplete (patient/family decision)	1	2	1	3	2	0	0	0	0	0	3	0	0	0
Incomplete (physician decision)	0	0	0	0	0	1	0	0	0	0	0	1	0	0
Palliative														
Complete	55	11	2	43	10	1	1	3	0	7	3	20	13	60
Incomplete (died)	4	0	0	3	0	0	3	0	0	3	0	1	0	5
Incomplete (patient/family decision)	4	3	0	9	5	1	0	0	0	0	1	3	7	2
Incomplete (physician decision)	5	1	0	3	0	0	0	0	0	1	0	0	2	2

Note: Abd = abdomen; Pab = posterior axillary boost area; Cerv = cervix; CW = chest wall; Esoph = esophagus; H/N = head and neck; IMC = internal mammary chain; Ov = ovaries; Sclv = supraclavicular region; Uter = uterus.

curative and palliative intent. Substantial success has been seen for curative patients still alive with cancer present from 2006 to 2008. The successful index of change is calculated to be +11.1% (index range, 25.7%-36.8%). This is even higher from 2007 to 2008, evident by the +15.9% rise (index range, 20.9%-36.8%). These rising indices are consistent with the reduction seen in the number of deaths from known disease with curative intent. For palliative patients, the total number of deaths from known disease has climbed markedly. Since 2006, the index has risen from 7.5% to 26.7% in 2008, yielding an increase nearly 3.6 times in magnitude, or +19.2%. Most of the patterns of other index groups have held steady for the most part. However, for the most recent year, both curative patients still alive and palliative patients now deceased show lower indices. Although that seems evident, one can also deduce an increase in the number of patients being seen who have higher staged disease with less prognostic hope for cure in the last 4 years. The PMMI for patients with palliative intent now dead, because of disease has increased.

It seems that when the disease is unknown, aggressive treatment has been offered with curative intent in the best hopes of providing a solution to tumor control. Although the statistic for unknown disease with curative intent resulting in death has increased, offering a different regimen may not have any morbidity benefit. In contrast to palliative care when disease is unknown, the death index is at the same level as prior years. It is not expected that common cancer types become more resistant to radiation, because each patient has disease independent of other patients and independent of the environment itself. Therefore, these results may generalize a reflection of fewer high-stage cancers being diagnosed in the area. Higher staged cancers could be caused by a lack of attention by patients with respect to immediate consultation with their physician specialists. Again, there is some viability to the consideration of more advanced imaging capabilities being made available currently, where staging and classification schema may have then resulted in a more accurate initial diagnosis and classification assignment. Trending for this PMMI becomes increasingly helpful to radiation oncologists in understanding and predicting the prognosis of patients both during and after treatment.

The internal outcome focus study expands the data of the PMMI into site-specific results. These are easily obtainable by keeping tabs on the total number of patients separately according to the physician's intent, for each site of treatment, and specifically for each completion or incompletion outcome. Examples of data used in annual tracking are exhibited in Table 1. Resulting percentage rate of occurrence calculations are shown in Table 2. As seen here in this region, more patients are presenting with disease in the lung (21%) and brain (13%) than any other site of treatment. Prostate cancer in men occurs at

Table 2. Artificial internal outcome focus study percentage results for 2009

	Brain	H/N	Breast	Lung/ Trachea	CW/Sclv Pab/IMC	Bladder	Ov/Uter/ Cerv/Endo	Shoulders	Prostate	Abd/ Esoph	Colon/ Rectum	Hips	Extremities/ Skin	Spine
% Curative														
Complete	92	92	98	94	94	50	88	100	100	100	83	75	100	80
Incomplete (died)		3		2			13				17			20
Incomplete (patient/family decision)	8	5	2	4	6									
Incomplete (physician decision)						50						25		
% Palliative														
Complete	81	73	100	74	67	50	25	100		64	75	83	59	87
Incomplete (died)	6			5			75			27		4		7
Incomplete (patient/family decision)	6	20		16	33	50					25	13	32	3
Incomplete (physician decision)	7	7		5						9			9	3
Case % Curative	16	71	97	58	67	50	67	40	100	31	82	14	68	7
Case % Palliative	82	29	3	41	33	50	33	60	0	69	18	86	32	93
% Anatomy is treated	13	8	9	21	7	1	2	1	7	2	3	4	10	11

Note: Abd = abdomen; Pab = posterior axillary boost area; Cerv = cervix; CW = chest wall; Esoph = esophagus; H/N = head and neck; IMC = internal mammary chain; Ov = ovaries; Sclv = supraclavicular region; Uter = uterus.

a rate of 7%, with breast cancer in women occurring at 9% in this community. For head and neck cancers specifically, 71% of cases are curative, with only 29% palliative. Completion rates for these are 92% and 73%, respectively. As one would expect, a greater number of incomplete treatments were documented for palliative cases than for curative cases. Lower levels of success across the board for curative completions mark a need to focus on education for patients and their families to reduce the number of patients having incomplete treatment by decision. The internal outcome focus study should always be evaluated coincident with each of the presented morbidity-mortality indexes, whereby reconsiderations on patient management and site specificity may be made possible.

CONCLUSIONS

This research focuses on annual internal studies within the clinical area. These include the morbidity and mortality review, as well as the internal outcomes focus study. Definitions are provided as well as a complete discussion of the ideal parameters to consider when constructing each of these. In general, data entry for these types of investigations are best conducted independently. If the anatomic location has a prescription specifically for it, then statistical tracking should be done for it separately. All of the statistical indices of interest can be derived from the data obtained during chart closeouts and follow-up review. The implementation of such design characteristics used may be of assistance to a center pursuing achievement of these requirements toward continuous quality improvement in external-beam radiation therapy. It further provides the educational tools necessary for the reader to mature expanded studies from it for advanced site-specific, outcome-specific, and prognostically designed analyses if sought after. One notable expansion to consider may include separate data for each radiation oncologist operating at the center. From this information, it is possible to detect hidden patterns of unequal referral, whereby one physician expects to receive the same number of patients as a colleague, but data show the contrary. It is also possible to provide trending for patient outcomes by comparing physician treatment aggressiveness. By having radiation oncologists review these annual morbidity and mortality indices and internal outcomes focus study data together, it should be observed that these methods are valued tools for revising dose prescription levels for better patient care.

ACKNOWLEDGMENTS

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