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Understanding Deviations from Clinical Practice Guidelines in Adult Soft Tissue Sarcoma

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Abstract

In recent years we have witnessed the increasing adoption of clinical practice guidelines (CPGs) as decision support tools that guide medical treatment. As CPGs gain popularity, it has become evident that physicians frequently deviate from CPG recommendations, both erroneously and due to sound medical rationale. In this study we developed a methodology to computationally identify these deviation cases and understand their movitation. This was achieved using an integrated approach consisting of natural language processing, data modeling, and comparison methods to characterize deviations from CPG recommendations for 1431 adult soft tissue sarcoma patients. The results show that 48.9% of patient treatment programs deviate from CPG recommendations, with the largest deviation type being overtreatment, followed by differences in drug treatments. Interestingly, we identified over a dozen potential reasons for these deviations, with those directly related to the patients' cancer status being most abundant. These findings can be used to modify CPGs, increase adherence to CPG recommendations, reduce treatment cost, and potentially impact sarcoma care. Our approach can be applied to additional diseases that are subject to high deviation levels from CPGs.

Keywords:

Physician's Practice Patterns [N04.590.748],
Practice Guideline [V02.515.500],
Sarcoma [C04.557.450.795],
Decision Support Techniques [L01.700.508.190],
Natural Language Processing [L01.224.065.580].

Introduction

The modern medical landscape is characterized by a plethora of different treatment options for almost indistinguishable clinical statuses. While the development of new treatment modalities is beneficial, it also poses challenges associated with the growing body of evidence regarding the outcomes of different treatments.

As a consequence of the complexity of treatment possibilities and the presence of widespread variation in medical practice, it has become clear that a large fraction of patients do not in fact receive the best possible care [1,2]. Deviations from optimal care are abundant in diseases where treatment efficacy varies as a result of subtle changes in the clinical scenario as well as in cases where clear scientific evidence is not present, as is often seen in cancer [3,4]. Therefore, an important question in medicine is what leads clinicians to prescribe treatments that do not adhere to best practice.

One approach to monitor deviations from standard medical practice is by assessing adherence to CPGs. CPGs are collective sets of treatment recommendations that attempt to capture the best medical practices for different pathologies [5]. CPGs are promoted as a means to decrease inappropriate practice variation and reduce medical errors [6]. It is generally thought that clinician adherence to CPG recommendations is the primary means to achieve this goal. High levels of adherence to CPGs may indicate optimal care, whereas low adherence rates may suggest sub-optimal treatment. In reality, however, deviation from CPGs often reflects the fact that CPGs cannot be exhaustive; it is not feasible to cover the entire combinatorial space of patient parameters. Deviations from CPG recommendations may thus be beneficial, and it is expected that clinicians will use their personal judgement to contextualize individual patient decisions. In light of the above, previous work identified several barriers to adherence including physician familiarity with the CPGs, physician attitudes towards the CPGs, environmental factors, CPG implementation factors and patient-related factors such as preference [7,8].

Monitoring compliance to CPGs in the clinical setting can be labor intensive. Therefore, in this study we strived to automate the characterization of adherence to CPGs using natural language processing, data modeling and comparison algorithms. Our vision was to computationally parse electronic health records (EHRs) containing both structured and unstructured data to quantify adherence levels, categorize the types of deviations from CPG recommendations, and finally identify the potential rationale for these deviations.

We demonstrate our approach using EHRs of patients diagnosed with adult soft-tissue sarcoma (STS). STS is a group of connective-tissue based cancers that account for roughly 1% of new cancer diagnoses with historical five year survival rates of slightly greater than 50% [9]. These cancers have diverse anatomical origins and can derive from multiple somatic cell types. The variety of histologies results in the presence of multiple drug options and the different anatomical locations offer multiple surgical possibilities. As STSs are rare cancers with numerous treatment options, it is not surprising that prescriptions for patients frequently deviate from CPGs, making STS an ideal use case to evaluate our methodology [10,11,12].

Methods

Description of concepts

The CPGs used in this study were developed by the Lombardy Oncology Network, a data sharing network that contains over

fifty care premises in Northern Italy. Patient data used in this work were gathered at the Fondazione IRCCS Istituto Nazionale dei Tumori (INT), a network member and thought leader, from November 2006 to November 2012.

The CPGs contained hundreds of clinical cancer presentations (conceptually similar to diagnosis) with matching recommended treatments. There are multiple recommended treatments for each clinical presentation. A single CPG recommendation was defined as the unique coupling of clinical presentation, recommended treatment, and start/end date. The study involved 1484 separate CPG recommendations.

Individual clinical presentations were modeled as a data structure of the following clinical fields: tumor anatomic location, tumor depth (deep/superficial), tumor grade, tumor size, disease status, tumor histological type (liposarcoma, etc.) and surgical status (tumor resectable/not resectable). A clinical presentation included all or a subset of the fields. This modeling approach is standard for CPGs, and is similar to that used by the National Comprehensive Cancer Network [13]. An example of an STS clinical presentation in the Lombardy CPGs is: "Patient with adult soft tissue sarcoma located in the limb or torso with a deep, high grade, ≥5cm, localized tumor".

Treatment programs (TPs) were defined as sequences of medical procedures (treatment elements), for example "Wide surgical excision with adjuvant/neo-adjuvant radiotherapy". A treatment element contained items such as drug administration, surgery, radiotherapy, and transplantation. The Lombardy CPGs contained recommended TPs for each clinical presentation.

Once a physician selected a particular clinical presentation from the CPGs, the matching TPs were presented via the local EHR system. Physicians were able to prescribe a TP that was discordant with CPG recommendations (Figure 1). In doing so, they entered their alternative TP in free-text form. The EHR system recorded this decision as well as additional relevant notes provided by the physicians.

Data regarding the treatment was also entered into the EHR system by caregivers during TP execution. We applied standard NLP methods on this data to deduce the actual TP that a patient underwent. The extracted TP was compared to the CPG recommended TPs to assess adherence. The actual TP was considered to deviate if it was discordant to CPG recommendations, regardless of whether the prescription was according to the recommended TPs or not (Figure 1).

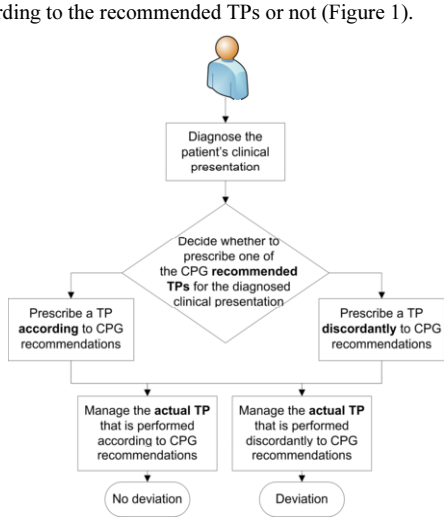

Figure 1 - CPG assisted decision making.

Application of NLP techniques

We applied NLP techniques on the EHR free text data to computationally retrieve the required information for this study. After Italian to English machine translation, we used the Unstructured Information Management Architecture (UIMA) framework to process unstructured information [14]. Our UIMA pipeline included tokenization, parts of speech (POS) tagging, normalization using standard terminologies in UMLS [15], entity and relationship extraction, semantic analysis, negation and disambiguation reasoning. Resulting structured annotations included drugs, diseases, procedures, symptoms, body regions and tumor characteristics. Relationship extractions were used to infer aspects such as the number of chemotherapy cycles, tumor size, tumor grade, and reasons for specific treatment prescription.

The IBM Advanced Care Insights platform (ACI) was used to run the UIMA framework. Within ACI, IBM Content Analytics Studio (ICA Studio) was used to build a Processing Engine Archive file (PEAR), which is a standard UIMA packaging format that can be deployed within any UIMA-compatible framework.

The basic building blocks of ICA Studio are dictionaries and rules. There are three types of rules: break rules that are used for tokenization, character rules that are used for pattern recognition of specific types of information such as dates, names and units, and parsing rules that are used to analyze tokens, other UIMA annotations, and their relationships.

ACI's built-in medical dictionaries contain RxNorm, SNOMED CT, ICD-9, ICD-10, LOINC, and HL7. We supplemented ACI with dictionaries containing chemotherapy drugs, local clinical studies, tumor parameters, and treatment reasons. Finally, ACI also contains entitiy mappings such as SNOMED CT to ICD-9 and ICD-9 to ICD-10.

Treatment program comparison

The results of the text analytics are structured annotations on the text. The annotations first need to be transformed to a pre-defined data model to enable advanced analyses. We therefore designed an actual TP model that defines the treatment which was given to patients (not shown here). The model was designed to enable comparison with the recommended TPs.

To categorize deviations, we identified the most similar recommended TP in the CPGs. The most similar recommended TP was found by assessing the degree of similarity between recommended and actual TPs. The differences between an actual deviating TP and its most similar recommended TP were classified into different categories.

The comparison approach used in this study had three stages. First, we analyzed the abundance of treatment elements to find extra or missing elements. We next used permutation comparison to detected changes in treatment element sequence. The final step was a comparison of the content of every treatment element itself; the specific properties of treatment element were compared. The third step enabled the detection of different chemotherapy drugs, different numbers of chemotherapy cycles, and different surgery types.

Extracting reasons for deviation

We used the same NLP techniques described above to extract reasons for deviation from CPGs. This was done by identifying relationships between extracted annotations using semantic parsing rules. For example, one can consider the following machine-translated sentence: "In light of extension of illness, the patient's age and preliminary activity of molecule in this particular histotype, starting chemotherapy

with gemcitabine". By detecting that the conjunction "in light of" connects the two parts of the sentence, we deduced that the first part of the sentence describes reasons for the given treatment, whereas the second part ("starting chemotherapy …") describes the treatment itself.

Manual validation

We performed manual validation of our computational results on a subset of randomly selected TPs (see results). Four human validators were exposed to the entire EHR records and CPGs. Different subsets of the validation dataset were allocated to each reviewer and results were compiled.

Results

Study setting, patient selection, and data cleansing

Our patient data contained adult STS patients treated at the Fondazione IRCCS Istituto Nazionale dei Tumori between November 2006 and November 2012. We acquired 5598 electronic patient discharge letters representing 2699 STS treatment programs on a total of 2151 different patients. 948 TPs with missing data were excluded consisting of: TPs that were follow-ups, where the actual TP was unknown, did not have at least one CPG recommendation due to CPG incompleteness, or were clinical studies not mentioned in the CPGs. This resulted in 1751 TPs consisting of 1431 patients for analysis (Table 1).

Table 1– Summary of TPs included in the study

Feature	Value
Number of TPs	1751
Male	957
Female	794
Duration	Nov 2006 – Nov 2012
Age range	18 – 100 (median 57)
Unique patients	1431

Quantifying factors that impact deviation frequency

Our computational approach identified deviations in 48.9% of the actual TPs, meaning that most given treatments were found to not fully comply with the CPG recommended TPs.

We next assessed non-clinical parameter correlation with deviation frequency. Strikingly, 35% of the TPs prescribed according to CPG recommendations in reality deviated from the CPG recommendations (Figure 2A). TPs that were prescribed discordantly to CPG recommendations did in fact deviate in 80% cases. Gender and age (cutoff set at median age) were not associated with deviation frequency.

Upon analysis of clinical parameters (Figure 2B), we observed that all disease and tumor parameters were associated with deviation frequencies, except for tumor location. This analysis portrays an expected trend in which poorer prognostic status (large, high grade, and deep tumors) is linked to substantially higher deviation levels. Indeed, the highest deviation frequency was found in metastatic disease (78%).

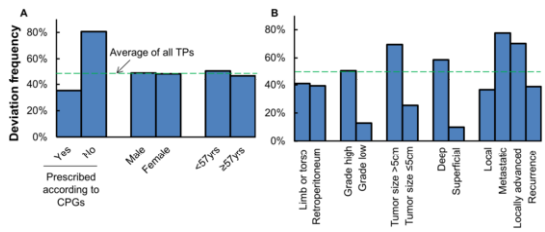

Figure 2 - Features associated with deviation frequency. (A) Demographic/adherence features (B) Clinical parameters. Not all features were specified in each TP. N=: limb/torso (1037), retroperitoneum (304), high gr (661), low gr (512), >5cm (371), ≤5cm (110), deep (445), superficial (331), local (1206), metastatic (359), locally adv. (57), recurrence (183).

Measuring prevalence of different deviation types

TP deviations can be classified using non-mutually exclusive categories. Tabel 2 presents the abundance of deviations that have added or removed treatment elements, exhibited differences in chemotherapy drugs, differences in number of chemotherapy cycles, and differences in surgery type.

The most abundant source of deviation was overtreatment, consisting of 39.7% of all cases in contrast to 12.7% for missing treatments. Notably, metastatic presentations had no excluded elements despite an overall average of 12.7% for all TPs. Also prominent was the observation that there was only a

Table 2 - Frequency of deviation types. Chemotherapy/surgery percentages shown with respect to TPs that included those elements.

Parameters	Added/Removed elements					Chemotherapy differences			Surgery differences	
	N (Dev TPs)	Added element	Missing element	Added and missing	Different order of elements	N (Dev TPs with chemo)	Different drug	Different cycles	N (Dev TPs with surgery)	Different surgery type
Prescribed according to CPGs	431	25.5%	17.6%	0.5%	13.9%	277	34.7%	36.8%	335	32.8%
Prescribed discordantly	426	54%	7.7%	1.6%	7%	301	44.2%	19.6%	239	16.3%
High grade	336	12.8%	24.1%	1.5%	17.6%	220	32.3%	35.5%	278	40.6%
Low grade	66	34.8%	10.6%	4.5%	7.6%	29	3.4%	0%	51	58.8%
>5cm size	258	13.6%	22.5%	0.8%	14%	138	27.5%	41.3%	225	50.2%
≤5cm size	28	46.4%	7.1%	3.6%	7.1%	19	5.3%	15.8%	23	39.1%
Deep	261	13%	23%	1.1%	13%	141	27%	39%	224	52.7%
Superficial	33	42.4%	18.2%	6.1%	15.2%	21	14.3%	14.3%	23	43.5%
Local	441	17.5%	20.6%	1.8%	17%	283	29%	31.4%	355	41.7%
Metastatic	279	57.3%	0%	0%	3.2%	232	10.3%	7.8%	113	0.9%
Loc. advan.	40	27.5%	37.5%	2.5%	12.5%	40	50%	12.5%	19	0%
Recurrence	143	41.3%	9.8%	2.1%	5.6%	98	48%	15.3%	84	16.7%
All TPs	857	39.7%	12.7%	1.1%	10.5%	578	39.6%	27.9%	574	26%

10.3% deviation rate of type 'different chemotherapy drug' for metastatic cases with administered chemotherapy. In general, disease parameters were more strongly associated with chemotherapy differences than surgical differences, with an exception being local/metastatic clinical presentations.

Identification of potential reasons for deviation

NLP parsing identified 1191 potential reasons for deviation among the 857 TPs that we labeled as deviations (average 1.4 per TP). 67.3% of the deviating TPs had one to four reasons and 29.7% had no identified reasons (Figure 3A).

Potential reasons for deviation were classified into five categories: cancer status, other clinical, current treatment related, previous treatment related, and patient preference related. Reasons for deviation that were based on cancer status represented the majority (59%) of all deviations (Figure 3B).

Deviation reasons were further classified into lower-level categories (Figure 3C). The cancer status category consisted of different tumor and disease progression parameters. Other clinically related reasons included demographics, oncological and non-oncological comorbidities, acute symptoms and overall clinical condition. The previous treatment related reasons include amount of previous treatment, poor previous response, previously severe side effects, and presence of residual margins after surgery. The patient preferences category included patient treatment requests or refusals. Lastly, current treatment related reasons consisted of anticipated treatment efficacy, impact on quality of life, and newly available clinical evidence. Deviations due to environmental constraints including lack of personnel or resources were rare and thus not presented.

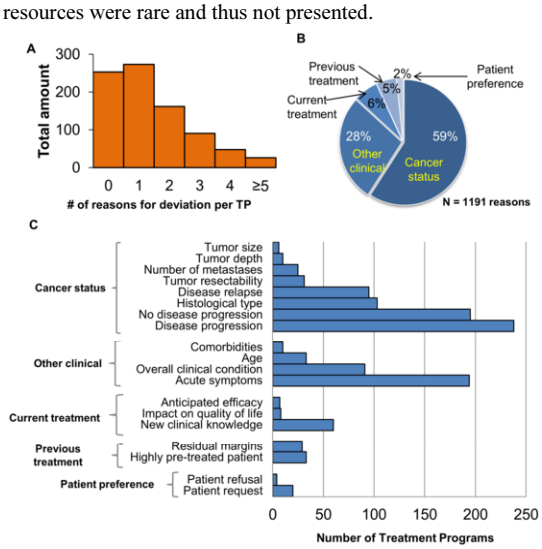

Figure 3 – Potential reasons for deviation. (A) Number of reasons of deviation per TP (N=857 deviating TPs). (B) Different categories of deviations. (C) Deviation subtype analysis (subtypes with n≥4 deviating TPs are shown).

The largest fraction of deviations appear to result from disease progression or a lack thereof, together with presence of acute symptoms. Interestingly, new medical knowledge was only a small fraction of potential deviation causes.

Manual validation

We performed manual validation on a dataset of 222 TPs that were randomly selected from the entire dataset. The validation dataset contained 136 TPs prescribed according to CPG recommendations and 86 discordant TPs.

We first searched for exact matches between NLP-retreived actual TPs to manually retreived TPs. Given this approach, minor or large differences between manually detected and NLP-retrieved actual TPs had the same effect on scoring. The recall for all TPs, TPs prescribed according to CPGs, and discordantly prescribed TPs was 0.71, 0.73, and 0.67, respectively. Chemotherapy cycles were not evaluated for comparison. The TP comparison framework detected differences between actual and CPG recommended TPs. As expected, manual validation showed that the comparison had rather high recall (0.88).

We also assessed deviation labeling. Deviation labeling relies on the accuracy of actual TP extraction and the TP comparison. We compared the quality of our deviation labeling algorithm to a default algorithm that labels TPs prescribed accordingly to CPG recommendations as 'no deviation' and discordantly prescribed TPs as 'deviation' (Table 3). The results show better performance in cases that were prescribed discordantly to the CPGs, while good recall was achieved in the remaining cases.

Finally, a random subset of 60 deviating TPs were selected from the validation dataset for manual analysis of detected reasons for deviation. Validation of detected reasons had the following recall: 0.67, precision: 0.78, and F1 score: 0.72.

Table 3 - Deviation labeling validation (algorithm vs default)

	Entire dataset (n=222)		**TP prescribed according to CPGs (n=136)**		**TP prescribed discordantly to CPGs (n=86)**	
	Alg	Def	Alg	Def	Alg	Def
Recall	0.87	0.62	0.80	NA	0.91	1
Prec.	0.65	0.66	0.47	NA	0.81	0.66
F1 val	0.74	0.64	0.60	NA	0.86	0.79

Discussion

In this work we developed computational techniques to characterize deviations from CPGs in adult STS across thousands of patient records. We identified deviations, classified them by types, and proposed reasons that may reflect the physicians rationale in deviation cases. Beyond the value of understanding clinical deviations, this analysis makes multiple findings that may be useful to sarcoma researchers and the decision support community.

One interesting finding was that approximately half (48.9%) of all TPs deviated from the CPGs. Noting the error present in NLP-based analysis, this value is comparable to a study published in 2012 that reported 54% adherence levels [10] and is higher than a study published eight years prior that had 32% [11]. While being a small sample size, this may suggest that compliance to CPGs is increasing for sarcoma over time.

In contrast to the above, we found that the current deviation level is roughly twice that of a recently published study showing 24% deviation frequency, a study whose data have included many of the same patients as in this work [12]. This discrepancy is due to the fact that deviations in the former study were defined as discordantly prescribed TPs, whereas in this study we analyzed whether the actual given TP deviated. This helps explain the observation that 19% of TPs originally prescribed discordantly to CPG recommendations were not in fact deviations. Conversely, we also found that 35% of all TPs prescribed according to the CPGs were actually deviations.

The observation that adherence to, or deviation from CPGs does not strongly predict if the administered TP adheres to the CPG, may have several causes. For instance, physicians may incautiously select a CPG recommendation with a genuine intent to write the actual prescription in free-text. Alternatively, CPG recommendations may not be clear and their selection may not be sufficiently simple. EHR quality may also play a role if detailed treatment documentation is challenging.

Deviation type analysis identified a large tendency to overtreat patients, representing 39.7% of deviation cases. Overtreatment (reviewed in reference [16]) was 3.1-fold more prevalent than missing treatments. The actual number is likely even higher since we manually observed upon inspection of EHR data that documents are missing for some patients. This issue was addressed by analyzing the treatment program fields, as these tend to summarize the complete course of prior treatment.

Overtreatment was especially evident for metastatic patients (Table 2), whom in general where prone to higher deviation levels (Figure 2). This is interesting when considering that metastatic patients had a relatively small amount of drug related deviations due to the large variety of different chemotherapy options at this disease stage. Deeper investigation of overtreatment cases can potentially assist in reducing treatment cost and improving quality of life.

Mining for deviation reasons can help inform physicians of their medical behavior during the decision making process. This knowledge can motivate specific questions that may impact care, for example why does tumor histological type potentially account for 8.5% of all deviations (Figure 3C).

Several factors that impacted our results warrant mention. First, as with most NLP based studies, our study was also subject to inaccuracies resulting from variability in the free-text representation of medical data. Second, our EHR-based dataset was composed of patient discharge letters, with an average of 2.6 documents per patient. As mentioned, a fraction of patients had missing discharge letters that we were not able to access. We partially addressed this issue by analyzing the treatment program fields. Finally, the study was performed assuming correctness of clinical presentations, although misdiagnosis is expected to be present in oncology care.

Our work focused on developing an integrated framework for understanding physician medical decisions in relation to CPG recommendations. In the future it may be possible to extend this analysis with outcome data, which could subsequently be integrated into EHRs to assist in decision making.

Conclusion

In this study we developed a methodology for a deeper understanding of adherence to CPG recommendations and implemented it in an adult STS use case. The resulting insights from this approach can be used to improve CPGs, to understand the decision making process of physicians, to identify cases where deviations may be beneficial, and to increase adherence to CPGs when deemed appropriate.

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