The Development and Application of an Oncology Therapy-Related Symptom Checklist for Adults (TRSC) and Children (TRSC-C)

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Abstract. *Background:* Studies found that treatment symptoms of concern to oncology/hematology patients were greatly under-documented in medical records: on average 11.0 symptoms by patient report versus 1.5 in medical records. Studies now indicate that a solution to this problem and improved patient outcomes is use of a quick, clinic-friendly, easy to use symptom checklist just before medical consultations with patients.

Purposes: Describe the oncology Therapy-Related Symptom Checklists for Adults (TRSC) and Children (TRSC-C). The TRSC has 25 items/symptoms and the TRSC-C 30 items/symptoms, and these items capture up to 90% of symptoms mentioned by patients. Measurement properties and applications with outpatients are presented. Informatics applications are indicated.

Methods: The TRSC was developed for adults (N=282) then modified for children (N=385). Statistical analyses have been done using correlational, epidemiologic, and qualitative methods. Extensive validation of measurement properties has been completed. Integration of the checklists into electronic/computer systems is proceeding.

Findings: Completed research has found high levels of patient/clinician satisfaction, no increase in clinic costs, and strong correlations of TRSC/TRSC-C scores with the number of patient symptoms documented/managed, functional status, and quality of life. A recently published sequential cohort trial with adult outpatients at a Mayo Clinic community cancer center found TRSC use produced a 7.2% higher patient quality of life, 116% more symptoms documented/managed, and higher functional status. Other TRSC/TRSC-C study findings are presented in papers in this special session.

Conclusion: A symptom checklist (TRSC/TRSC-C) can facilitate monitoring, management of symptoms, and informatics applications helpful to patients and clinicians.

Implications: Gathering information about symptom occurrence and severity can optimize cancer care. TRSC studies suggest that electronic applications are a next step.

1   Background

In the USA, the incidence of cancer has been increasing for many years, treatment costs rising, and, consequently, aggregate expenditures growing. In recent years, incidence rates of some adult cancers have slowed, but treatment costs continue to rise along with the use of newer and more expensive interventions. Unfortunately, the use of newer interventions and increased survival has brought with them the increased likelihood of negative side effects of treatment affecting patient symptoms and outcomes. Many patients leave treatment due to negative side effects. Despite the apparent slowing incidence of adult cancers, recent statistics suggest that incidence rates of cancers in children and adolescents are increasing as is treatment costs and concerns about better management of patient treatment symptoms. Recent data indicate that the costs of treating childhood cancers may exceed treatment costs for adults.

2   Recognition of the Need for Improved Management of Patient Symptoms

Symptoms arising from use of oncology therapies require careful monitoring for problems of adjustment to treatment regimens and for identification of adverse effects on patients. Since the 1980s, clinical guidelines in the USA have strongly urged the monitoring of subjectively reported treatment symptoms as stated by patients; however, certain factors have worked against such systematic monitoring. First, the average time spent with patients by physicians during consults is around 19 minutes but frequently less than 15 minutes, which greatly narrows time for conversations. Very limited time may be spent on topics specific to these visits [1]. Second, the clinical interview is often unstructured with patient's being asked "what problems have you had" often without any prompts related to "problems" that may be of special concern to treatment of the patient. Third, at least until recently, the collaborative role of the patient has been lightly regarded in clinical training, in the literature, and in practice. Fourth, although changing under computerization, medical records are often poorly and inconsistently maintained. For these reasons and consistent with anecdotal reports, many observers of health care in the USA believed that patient symptoms associated with therapies were under-documented in medical records. Consequently, a valuable resource for improved treatments and outcomes, symptoms of concern to patients, was being underutilized or even ignored.

One of the earlier studies of the collection and use of patient reported symptoms in the USA was an oncology nursing study by Youngblood et al. in 1994 [2]. The study examined the medical records of 91 patients who after clinical consultation were asked to respond to the presence and intensity of any of 37 symptoms that were of concern to them. Patients' medical records recorded only 1.5 symptoms on average (range 0-9; SD=1.6), but on average these same patients checklisted 11.0 symptoms of concern to them (range 0-37; SD=8.0). Many of the symptoms "missed" could have led to substantial changes in therapy and treatment outcomes.

3   Creation of the Therapy-Related Symptom Checklist for Adults (TRSC)

A year following the above report another study was undertaken to develop a tool or checklist that could be readily used in oncology outpatient clinics. Essential requirements of such a tool are that it can be quickly answered, be easily understood by patients, and be comprehensive in terms of checklisted symptoms. If a tool meets all these criteria, it is "clinic friendly" in that it can be readily answered by patients in busy clinics prior to their consultation with physicians or nurses.

The tool used by Youngblood et al. consisted of 37 items or symptoms drawn from Eastern Cooperative Oncology Group (ECOG) documents and the clinical experiences of the authors [3]. It was decided to obtain a large sample using this tool, subject the data collected to analysis, and determine whether a clinic friendly checklist could be produced. Two hundred eighty-two patients 18-83 years of age undergoing chemo, radiation, or combined therapies at a cancer center in the Midwest USA answered the 37 item checklist that included spaces for patients to add symptoms if they desired. Few symptoms were added; therefore, these were not included in the analysis. (See Appendix A)

An anti-image correlation matrix was obtained, and measures of sampling adequacy (MSA) and the Kaiser-Meyer-Olkin (KMO) were calculated [4]. Nine of the 37 items (symptoms) had MSA <0.70 and were dropped. The elimination of these items raised the KMO from 0.7984 to 0.8368. Data were subjected to principal components analysis using SPSS/PC+ Version 5.0 with results checked against routines in SYSTAT and Stata. Principal components were varimax rotated using the Jolliffe criterion, which is conservative in that more components will be retained than by using alternative criteria, and items will not be prematurely excluded from analysis [5]. All items with component loadings ≥ 0.50 were retained. This led to an additional 3 items or symptoms being dropped from the new tool. The new tool called the Therapy-Related Symptom Checklist (TRSC) has 25 items or symptoms.

The TRSC accounted for 78.8% of the variance in the study sample. Its Cronbach's alpha was 0.85, and it correlated 0.97 with summated symptom concern scores (SC) of patients on the larger 37 item checklist. It discriminated well between patients in radio and chemotherapy with 79% of patients correctly classified in a linear discriminant analysis. The SC correlated significantly and in the correct direction with the functional status of patients on the Karnofsky scale (r=-0.35, p<.001).

Experiences using the TRSC in clinical settings are noted briefly below and in a paper with references by Phoebe Williams, Leticia Lantican, Julia Bader, and Daniela Lerma in this Special Session. To date, all patients and clinicians (physicians and nurses) have reported highly favorable experiences using the TRSC in outpatient clinics.

4   Creation of the Therapy-Related Symptom Checklist for Children (TRSC-C)

After the successful use of the TRSC in a number of clinical settings, it was decided to produce a children's version to be called the TRSC-C or the Therapy-Related Symptom Checklist for Children for use in pediatric and adolescent oncology clinics [6]. Funding support to produce such a tool was provided by the Alex's Lemonade Stand Foundation in Philadelphia, Pennsylvania, USA. The study to produce a "calibrated" instrument for children began in 2006. It involved 385 children (5-11 years, n=222) and teens/adolescents 12-17 years, n=163) at oncology outpatient clinics in 5 university affiliated children's hospitals in the central, eastern, western, and southeastern USA.

A checklist with 34 symptoms was produced. The same system as with the TRSC was used on this checklist to score presence and intensity of each symptom. This list contained most of the 25 items on the TRSC plus other items mentioned in the literature and that the nurses and physicians at the 5 participating institutions believed to be useful for monitoring the symptoms of children with cancer. The items or symptoms printed on the checklist included the symptom followed by "kid-friendly" terms describing the symptom. Data were collected from children and parents participating with their children at the outpatient clinics. Teenagers generally preferred to answer the checklist themselves.

The checklist collected from children and teens were analyzed as follows. After a Bartlett test of sphericity supported the application of factor or principal component analysis to the data, the Kaiser-Myer- Olkin measure of sampling adequacy (KMO) was calculated. None of the items or symptoms had a KMO < 0.80; therefore, a principal components factor analysis (pcfa using Stata version 11.1) was done using all 34 items. Factors (components) were retained if they had eigenvalues of 1.00 or greater. After the varimax rotation, items were considered to load on those factors on which their loadings were $\geq$ 0.40. All but 4 of 34 items possessed adequate loadings and were retained on the new checklist. Therefore, the new TRSC-C has 30 symptoms or items. (See Appendix B)

The Cronbach's alpha of the TRSC-C was 0.91. Summated TRSC-C scores correlated significantly with measures of functional status (r=-0.32, p=0.02). The correlation of the TRSC-C with a well known measure of pediatric quality of life, the PedsQL, was r=-0.68, p<0.0001 [7]. The TRSC-C accounted for 53% of the variance in the study sample, since children and teens tended to be somewhat heterogeneous groups. Older patients reported somewhat higher mean symptom concerns on 11 of the 30 symptoms on the checklist. For this reason, it has been suggested that the checklist use be examined carefully when used with children and teens.

Experiences using the TRSC-C in clinical settings are noted briefly below and in a paper with references by Phoebe Williams, Ubolrat Piamjariyakul, and Jenna DeGennaro in this Special Session. To date, all patients and clinicians (physicians and nurses) have reported highly favorable experiences using the TRSC-C in outpatient clinics.

5   Use of Checklists in Different Settings

Both checklists have been used in clinical settings with favorable comments received from clinicians and patients. The TRSC and TRSC-C are available in Spanish language versions, Chinese, Pilipino, Bahasa Indonesia, and Thai versions have been used in differing cultural settings. Clinicians have found that the checklists can be used for "anticipatory" guidance with patients; that is, discussions with patients can become more focused and deal explicitly with symptom management and treatment concerns.

Recently, a published study done at a Mayo Clinic community based outpatient cancer center has shown that use of the TRSC during treatment can improve the number symptoms documented and managed in the medical record by 116%, significantly improve (both clinically and statistically) the health related quality of life of patients (HRQL), and significantly improve the functional status of patients [8]. This finding is consistent with a call by WHO and others for a "checklist manifesto" to use checklists to avoid surgical and other medical errors [9]. This call should be extended to include all kinds of services provided directly to patients that might be improved through presentation of simple lists of items, procedures, or activities that might enhance patient recall, clinician-patient communications, and anticipatory guidance.

Although the TRSC was originally developed to meet needs for better symptom documentation and improved clinician-patient communication, the authors and users of the TRSC and TRSC-C have noted that other possibilities for use of the instruments exist. First, the checklists themselves correlate highly with quality of life measures, which suggest that the TRSC might be able to be used as a proxy measure thereby reducing paperwork burdens. Second, although it cannot be discussed in this paper, the TRSC and TRSC-C appears successful in capturing symptom clusters, which is a new and important area in the management and treatment of cancer. Third, the checklists allow symptoms to be systematically monitored across time.

6   Need for Computerization and Conclusions

Early studies were done of TRSC use at distant clinics using two-way video communications and the collection and storing of data in a computer. These studies indicated that both clinicians and patients were very favorable to the use of the TRSC, which appeared much more clinic friendly and relevant to treatment than previously used tools. Additionally, it was found that computerization allowed both clinicians and patients to easily and rapidly review symptoms related to previous and on-going treatments [10]. It is probably clear to most conference participants that the other possibilities for use of the TRSC or TRSC-C just mentioned above would be greatly enhanced by computerization as would clinical interactions between patients and clinicians.

The paper presented at this Special Session by Farrokh Alemi, Hosai Hesham, Arthur Williams et al. describe a pilot study now underway to provide a phone-computer based system that will link patients to clinicians and provide flags to indicate when

patients may need to be called by a clinician. Work is now underway to expand TRSC and TRSC-C applications through applied informatics and clinical trials.

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Appendix A: TRSC Form for Adults

THERAPY-RELATED SYMPTOM CHECKLIST (TRSC)

Name: _____ ID #_____ Date:_____

PLEASE **CHECK** THE <u>PROBLEMS</u> YOU HA VE HA D <u>IMMEDIATELY A FTER A ND SINCE YOUR L AST TREATMENT</u>. P LEASE <u>CIRCLE</u> HOW S EVERE T HE PROBLEM WAS ACCORDING TO THE FOLLOWING SCALE:

0 = NONE   1 = MILD   2 = MODERATE   3 = SEVERE   4 = VERY SEVERE

<u>**CHECK**</u> ☒	<u>EXAMPLE</u> **Pain**	<u>Degree of Severity **(CIRCLE)**</u>				
		0	**1**	**2**	**③**	**4**
☐	Taste Change	0	1	2	3	4
☐	Loss of appetite	0	1	2	3	4
☐	Nausea	0	1	2	3	4
☐	Vomiting	0	1	2	3	4
☐	Weight loss	0	1	2	3	4
☐	Sore mouth	0	1	2	3	4
☐	Cough	0	1	2	3	4
☐	Sore throat	0	1	2	3	4
☐	Difficulty swallowing	0	1	2	3	4
☐	Jaw pain	0	1	2	3	4
☐	Shortness of breath	0	1	2	3	4
☐	Numbness in fingers and/or toes	0	1	2	3	4
☐	Feeling sluggish	0	1	2	3	4
☐	Depression	0	1	2	3	4
☐	Difficulty concentrating	0	1	2	3	4
☐	Fever	0	1	2	3	4
☐	Bruising	0	1	2	3	4
☐	Bleeding	0	1	2	3	4
☐	Hair loss	0	1	2	3	4
☐	Skin changes	0	1	2	3	4
☐	Soreness i n ve in where c hemo-therapy was given	0	1	2	3	4
☐	Difficulty sleeping	0	1	2	3	4
☐	Pain	0	1	2	3	4
☐	Decreased interest in sexual activi-y	0	1	2	3	4
☐	Constipation	0	1	2	3	4
	Other problems (please list below)					

☐	_____	0	1	2	3	4
☐	_____	0	1	2	3	4
☐	_____	0	1	2	3	4
☐	_____	0	1	2	3	4

Appendix B: TRSC-C Form for Children and Parents

THERAPY-RELATED SYMPTOM CHECKLIST FOR CHILDREN ANDN PARENTS (TRSC-C)

Name: _____ ID # _____ Date: _____

Age: _____ Gender: Male _____ Female _____

PLEASE **IDENTIFY below** THE P ROBLEMS YOU H AVE H AD IMMEDIATELY AFTER AND SINCE YOUR LAST TREATMENT. PLEASE **CIRCLE** HOW SEVERE THE PROBLEM WAS ACCORDING TO THE FOLLOWING SCALE:

0=NO SYMPTOM	1 = A LITTLE BIT	2 = QUITE A BIT	3 = A LOT	4 = A WHOLE LOT

EXAMPLE	CIRCLE HOW SEVERE				
Pain	0	1	2	③	4
Loss of Appetite [Not feeling hungry; Eat less; Not feel like eating]	0	1	2	3	4
Nausea [Feel like throwing up; Upset stomach; Stomach hurts]	0	1	2	3	4
Vomiting [Throwing up]	0	1	2	3	4
Weight Loss [Losing weight; Feel skinnier]	0	1	2	3	4
Sore Mouth [Mouth hurts; Hurts to eat]	0	1	2	3	4
Difficulty Swallowing [Hard to swallow; Hurts to swallow]	0	1	2	3	4
Sore Throat [Throat hurts]	0	1	2	3	4
Jaw Pain [Jaw hurts; Hurts to chew or yawn]	0	1	2	3	4
Cough [Coughing much]	0	1	2	3	4
Shortness of Breath [Hard to breath; Breathe faster]	0	1	2	3	4
Feeling Sluggish [Feel very tired; Feel lazy]	0	1	2	3	4
Depression [Feel sad a lot; Cry more]	0	1	2	3	4
Difficulty Concentrating [Hard to think; Hard to pay attention]	0	1	2	3	4
Difficulty Sleeping [Hard to go to sleep; Hard to stay asleep]	0	1	2	3	4
Fever [Feel very hot; High temperature]	0	1	2	3	4
Bruising [Dark spots on skin; Bruise easily]	0	1	2	3	4
Bleeding [Bloody nose; Bleed easily from cuts, scratches, or when brushing teeth]	0	1	2	3	4
Hair Loss [Hair falling out; Losing hair]	0	1	2	3	4
Skin Changes [Skin feels dry or red; Skin feels different]	0	1	2	3	4
Pain [It hurts]	0	1	2	3	4
Numbness in Fingers and Toes [Tingling fingers/ toes; fingers/ toes "falling asleep"; Fingers/ toes feel cold]	0	1	2	3	4
Constipation [Hard to "poop"]	0	1	2	3	4
Sweating	0	1	2	3	4
Itching [Want to scratch skin]	0	1	2	3	4
Hard to urinate [Hard to "pee"]	0	1	2	3	4
Afraid [Feel nervous; worried]	0	1	2	3	4
Headache [Head hurts]	0	1	2	3	4

Irritable [Feel upset easily; get mad easily]	0	1	2	3	4
Agitation [Feel restless; can not stay still]	0	1	2	3	4
Tripping or Falling	0	1	2	3	4
Other (List) _____	0	1	2	3	4
Other (List) _____	0	1	2	3	4
Other (List) _____	0	1	2	3	4