

CCSS Therapy Working Group

- Temporally limited, but critical to all aims of the CCSS
- Immediate tasks:
 - Review and advise on current CCSS "MRAF"
 - Drugs (doses and exposure)
 - XRT
 - Surgery
- Develop plans for quality control of therapeutic data abstracted at centers

Chemo/XRT/Surgery Working Group:

Reconvened October 2005, August 2007

Current MRAF (circa 1990)

Abstracts chemotherapy, surgery, some radiation detail

Areas to address:

- process of registration
- chemotherapy content
- cumulative dose agents
- radiation process
- surgery process
- data submission
- data processing / editing
- quality control

University of Minnesota

CCRF Epidemiology Research Unit Division of Epidemiology/Clinical Research Department of Pediatrics

Suite 300 1300 S. Second St. Minneapolis, MN 55454

00083

AS MEDICAL CENTER, HOUSTON CHILDREN'S HOSPITAL, DENVER CHILDREN'S HOSPITAL OF CHILDREN'S HOSPITAL OF CHILDREN'S HOSPITAL & MEDICAL CENTER, SEATTLE HOSPITAL & PHILTIPLE HOSPITAL & MEDICAL CENTER, SEATTLE HIGGS CHILDREN'S MEDICAL HIGGS CHILDREN'S MEDICAL HIGGS CHILDREN'S MEDICAL HIGGS CHILDREN'S MEDICAL HIGGS CHILDREN'S MEDICAL, AND ANDERSON CANCER CENTER, NEW YORK, MINNEAPOLIS CHILDREN'S NYTER MOTT CHILDREN'S HOSPITAL, ROBANDOLIS ST. LEN'S RESEARCH STUTTE HASPITAL AND ARBOR CHILDREN'S HOSPITAL, ROBANDOLIS ST. LEN'S RESEARCH STUTTE HASPITAL AND AND ARBOR CHILDREN'S HOSPITAL, ROBANDOLIS ST. LEN'S RESEARCH STUTTE HASPITAL AND AND ARBOR CHILDREN'S AN FRANCISCO OF ALABAMA, BIRMINGHAM UNIVERSITY OF MINNESOTA, MINCAPPOLIS "UT-SOUTHWESTERN ENTER, DALLAS ROSWELL PARK, BUFFALO HOSPITAL FOR SICK CHILDREN, TORONTO

Medical Records Abstraction Form

			(Please print)	
н	ospital ID #			
	Is this	treatment for the initial can	cer diagnosis?	
	_	Yes No 1		
		- If no, number of new tumor	r (e.g., second, third maligna	ancy)
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Initial Patient Registration Data

- Diagnostic Data Originally Collected:
 - ICDO Code (currently ICDO-2)
 - Diagnosis (written field)
 - Metastatic (yes/no)
 - Site of primary tumor (text field)
 - Date of Diagnosis

Considerations:

- Next generation will be computerized entry: immediate feedback for "out of range" entries
- Improve site specificity, stage, include laterality
- Limit acceptable ICDO codes (challenge leukemia NOS)



CCSS-2 Patient Registration Data

Diagnostic Drop Downs for CCSS-2:

- [1] Leukemia
- [2] CNS (limited to Ependymoma, Medulloblastoma, Glioma; was open to all CNS tumors in CCSS-1)
- [3] Hodgkin Disease
- [4] NHL
- [5] Wilms' Tumor (was open to all renal tumors)
- [6] Neuroblastoma
- [7] Rhabdomyosarcoma (was all STS prior)
- [8] OGS / Ewings (all bone prior)
- Restricted use of non-specific codes
 - Active "challenging" through dialogue boxes
 - Locating most common diagnoses at the top



CCSS-2 Patient Registration Data

- Diagnosis / demographics alone needed for initial case selection
- Additional Information on "cases" collected with MRAF
 - Location
 - CCSS-2 will have improved site / laterality detail via drop down menus that are site specific
 - Stage / Metastases
 - Leukemia N/A
 - CNS Local / Intra-axial / Extra-axial
 - HD Ann Arbor Staging
 - NHL Local / Disseminated
 - NBL Local / Regional / Metastatic
 - Wilms' NWTS Staging
 - Rhabdomyosarcoma Local / Regional / Metastatic
 - Bone Local / Regional / Metastatic
 - All of the above was accomplished in the MRAF, and not necessary in the registration database

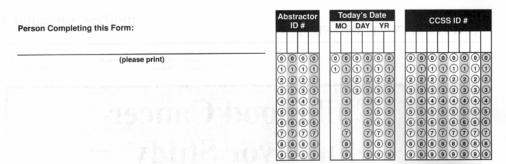


CCSS-2 Medical Records Abstraction Form (MRAF)

- Reviewed at Memphis investigator meeting
- Series of email follow-ups with committee members
- Summary of modifications
 - Move to computerized format
 - Drug modifications for more current cohort
 - Additions / deletions
 - Immunotherapy & Other agents sections to be added
 - Surgical Abstraction to take place at coordinating center
 - Additional XRT information to be collected to include location and name of treatment facility
 - Will be added to current version

CCSS-2 Medical Records Abstraction Form (MRAF)

Specific Recommendations August 2007



Chemotherapy

Did this individual have chemotherapy?

○ No ○ Yes Go to Page 7, Surgical Procedures

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I. Protocol Information - Indicate all standard protocols this patient was placed on.

Study Group CCG POG SWOG CALGB	St. Jude Other None
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7	7	7	7	7	7	(7) (8)	7	(8
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Page 2:

Chemotherapy: yes/no

Protocol information

Recommendation:

- record completed for each treatment plan (this means a new one for a relapse or new cancer) - accepted
- start/stop dates reflect planned therapy
- continue to collect protocol identification (but probably only need one for each treatment plan) – will collect with each new treatment plan

Need to keep dose/bsa accurate as patients grow

II. Chemotherapy Information (exposure)

Please indicate chemotherapies use	ed and routes	given.	discor	nis drug ntinued toxicity?		Route of Ad (Mark all t	ministratior hat apply)	'
	No	Yes	No	Yes	IV/IM	Sub-Q	Oral	
Actinomycin-D	0	0	0	0	0	0	0	(
Adenine Arabinoside (Ara A)	0	0	0	0	0	0	0	(
m-AMSA (Amascrine)	0	0	0	0	0	0	0	(
AZQ (Diaziquone)	0	0	0	0	0	0	0	(
5-Azacytidine	0	0	0	0	0	0	0	(
BCNU (Carmustine)	0	0	0	0	0	0	0	(
Bleomycin	. 0	0	0	0	0	0	0	(
Busulfan	0	0	0	0	0	0	0	(
Carboplatin	0	0	0	0	0	0	0	(
CCNU (Lomustine)	0	0	0	0	0	0	0	(
Chlorambucil	0	0	0	0	0	0	0	(
Cis-Platinum	O	0	0	O	0	O	Ŏ	(
Cyclocytidine Hydrochloride	0	0	0	0	0	Ö	O	(
Cyclophosphamide (Cytoxan)	0	0	O	O	O	0	O	(
Cytosine Arabinoside (Ara-C)	0	0	0	Ŏ	0	O	Ö	(
Daunorubicin (Daunomycin)	O	O	0	O	O	O	O	(
Deoxycoformycin	0	0	0	0	O	Ö	Ŏ	(
Dexamethasone	O	0	0	Ö	Ŏ	Ö	Ô	(
Doxorubicin (Adriamycin)	Ö	O	O	Ŏ	Ö	Ö	Ö	(
DTIC	O	Ŏ	O	Ŏ	Ŏ	Ŏ	Õ	(
5-FU (5 Fluorouracil)	0	Õ	O	Ŏ	Ŏ	Ŏ	O	(
Fludarabine phosphate	Ô	0	Ô	Õ	0	Ŏ	Ŏ	(
Homoharringtonine	0	0	O	Õ	Ŏ	Õ	O T	(
Hydroxyurea (Hydrea)	Ô	O	Õ	Ŏ	Ŏ	Ö	Õ	(
Idarubicin	0	0	0	Õ	O	Ö	O	(
Ifosfamide	0	0	O	O	O	0	Ö	(
L-asparaginase	0	O	0	Õ	Õ	Õ	Ô	(
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Methotrexate	Ö	0	0	Ŏ	Ŏ	Ŏ	Ŏ	(
Mithramycin	0	Õ	Ŏ	Ŏ	Ŏ	Ö	Ö	(
Myeleran	Ŏ	0	0	Ö	O	Ö	Ö	(
Nitrogen Mustard	0	0	0	0	0	0	Ö	-
Prednisone	Ö	0	0	Ö	O	O	Ö	(
Procarbazine	0	0	0	Ö	O	0	0	-
Retinoic Acid	Ŏ	0	Ô	Ö	0	Ö	Ö	(
6-Thioguanine (6 TG)	0	0	0	0	0	O	0	(
ThioTepa	Ŏ	Ö	0	ŏ	Ö	Õ	O	(
Vinblastine (Velban)	Ö	0	0	0	0	Ö	0	-
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VM-26 (Teniposide)	0	0	0	0	0	0	0	(
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Page 3: Chemo Exposures

Recommendations:

Add: Mitoxantrone, ARA-G, Topotecan, Temozolomide, Irinotecan, Gemcitabine, Gleevec, Fenretinide, Vinorelbine, Taxol, Taxotere,

Add an Immunotherapy Section Monoclonals: Mylotarg, Rituxan: IL2, IFN, ATG, Campath, Other

Add "Other agents": CSA, MMF, Tacrolimus, Sirolumus, Zinecard, Mesna, Growth factors (GCSF, GMCSF, Erythropoietin) II. Chemotherapy Information (exposure)

Please indicate chemotherapies use	ed and routes	given.	disco	nis drug ntinued toxicity?		Route of Administration (Mark all that apply)		
	No	Yes	No	Yes	IV/IM	Sub-Q	Oral	
Actinomycin-D	0	0	0	0	0	0	0	
Adenine Arabinoside (Ara A)	0	0	0	0	0	0	0	
m-AMSA (Amascrine)	0	0	0	0	0	0	0	
AZQ (Diaziquone)	0	0	0	0	0	0	0	
5-Azacytidine	0	0	0	0	0	0	0	
BCNU (Carmustine)	0	0	0	0	0	0	0	346
Bleomycin	. 0	0	0	0	0	0	0	
Busulfan	0	0	0	0	0	0	0	1986
Carboplatin	0	0	0	0	0	0	0	
CCNU (Lomustine)	0	0	0	0	0	0	0	
Chlorambucil	0	0	0	0	0	0	0	
Cis-Platinum	0	0	0	0	0	0	0	III EK
Cyclocytidine Hydrochloride	0	0	0	0	0	0	0	
Cyclophosphamide (Cytoxan)	0	0	0	O	O	Ŏ	Ö	REFE
Cytosine Arabinoside (Ara-C)	0	0	0	Ŏ	O	O	0	
Daunorubicin (Daunomycin)	0	0	0	0	0	0	0	999
Deoxycoformycin	0	0	0	0	0	0	0	
Dexamethasone	0	0	0	0	0	Ŏ	Ŏ	1000
Doxorubicin (Adriamycin)	0	0	0	0	0	0	0	
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5-FU (5 Fluorouracil)	0	0	0	0	0	Õ	0	
Fludarabine phosphate	0	0	0	0	0	Ŏ	Ŏ	
Homoharringtonine	0	0	0	0	0	Õ	0	
Hydroxyurea (Hydrea)	0	0	0	0	0	0	0	
Idarubicin	0	0	0	0	0	0	0	
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L-asparaginase	0	0	0	0	0	Õ	0	
Melphalan	0	0	0	0	0	Ŏ	Ŏ	
6-Mercaptopurine (6 MP)	0	0	0	0	0	0	0	
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Nitrogen Mustard	0	0	0	0	0	0	0	70 %
Prednisone	0	0	0	0	0	0	0	31817
Procarbazine	0	0	0	0	0	0	0	0,7
Retinoic Acid	0	0	0	0	0	0	0	J. P. 181
6-Thioguanine (6 TG)	0	0	0	0	0	0	0	
ThioTepa	0	0	0	O	0	Ŏ	Ö	SOFF
Vinblastine (Velban)	0	0	0	Ö	O	Ŏ	Ö	
Vincristine	Ŏ	O	O	Ŏ	O	Ŏ	Ŏ	
VM-26 (Teniposide)	0	0	0	0	0	O	Ö	
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Page 3: Chemo Exposures

Recommendations:

Drop: ARA-A, Amascrine, AZQ, Cyclocytidine, Deoxycoformycin, Homoharringtonine, Myeleran, Mithramycin

Discontinued due to toxicity column can be dropped

III. Specific Agents

Codes for Specific Agents:

01 Actinomycin-D	08 CCNU (Lomustine)	15 Doxorubicin (Adriamycin)	22 Myeleran
02 BCNU (Carmustine)	09 Cyclophosphamide (Cytoxan) - Oral	16 Idarubicin	23 Nitrogen Mustard
03 Bleomycin	10 Cyclophosphamide (Cytoxan) - IV	17 Ifosfamide	24 Procarbazine
04 Busulfan	11 Cytosine Arabinoside (Ara-C) - IV/IM	18 Melphalan	25 Thiotepa
05 Carboplatin	12 Cytosine Arabinoside (Ara-C) - IT	19 Methotrexate - IV	26 VP 16 (Etoposide) - Oral
06 Chlorambucil	13 Cytosine Arabinoside (Ara-C) - Sub Q	20 Methotrexate - IM	27 VP 16 (Etoposide) - IV
07 Cis-platinum	14 Daunorubicin (Daunomycin)	21 Methotrexate - IT	28 VM 26 (Teniposide)

For the agents listed above, please supply the following information.

1.	Drug #	Started MO DAY YR		Last Dose MO DAY YR			Cumulative Total Dose	Body Surface Area	Weight (kg)
Specify:	00	000	0000	00	00	00	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0		00000
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	Date		O	Body	
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3. Drug	Date Started	Last Dose	Cumulative	Body Surface	Weight (kg
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No dose data (enter 99999) (9) (9)	8 8 8 8	8 8 8 8	8888	8 . 8 8	888

Pages 4-6: Chemotherapy Cumulative Doses

Recommendations:

- Drop: myeleran, oral
 Cytoxan, all cytarabrine, IM methotrexate
- Add: Mitoxantrone,
 Epirubicin, Doxil,
 (anthracycline); Vincristine
 (late neuropathy), Nalerbine
 (AraG / Compound 506)
- Cumulative doses: anthracyclines, alkylators, Methotrexate, Busulfan, platinum, VP-16 /VM-26
- Double check IT-MTX

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III. Specific Agents

Codes for Specific Agents:

01 Actinomycin-D	08 CCNU (Lomustine)	15 Doxorubicin (Adriamycin)	22 Myeleran
02 BCNU (Carmustine)	09 Cyclophosphamide (Cytoxan) - Oral	16 Idarubicin	23 Nitrogen Mustard
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05 Carboplatin	12 Cytosine Arabinoside (Ara-C) - IT	19 Methotrexate - IV	26 VP 16 (Etoposide) - Oral
06 Chlorambucil	13 Cytosine Arabinoside (Ara-C) - Sub Q	20 Methotrexate - IM	27 VP 16 (Etoposide) - IV
07 Cis-platinum	14 Daunorubicin (Daunomycin)	21 Methotrexate - IT	28 VM 26 (Teniposide)

	Date			Body	
1. Drug	Started	Last Dose	Cumulative	Surface	Weight (kg)
#	MO DAY YR	MO DAY YR	Total Dose	Area	
Specify: Total dose abstracted Total dose, some estimated Incomplete or Partial dose Partial dose (enter 99999) 0 0 0	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	Indicate Dosage	· 0 · 0 0 · 0 0 · 0 0 0 · 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0
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Specify: Total dose abstracted Total dose, some estimated Incomplete or Partial dose No dose data (enter 99999)	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 0 0 1 1 1 1 1 1 2 2 2 2 2 2 3 3 3 3 3 4 4 4 5 6 6 6 6 6 7 7 7 7 8 8 8 8 8 8 9 9 9	Indicate Dosage	0 · 0 0 1 · 1 1 2 · 2 2 3 · 3 3 4 · 4 4 6 · 6 6 6 · 6 6 7 · 7 7 8 · 8 6 9 · 9 0	0000 1110 2220 3330 4440 6560 7770 8660 900
3. Drug #	Date Started MO DAY YR	Last Dose MO DAY YR 0 0 0 0 0 0 0 1 1 1 1 1 1 2 2 2 2 2 2	Cumulative Total Dose Indicate Dosage 0 0 0 0 0 1 1 1 2 2 2 2 2	Body Surface Area 0 • 0 0 1 • 1 1 2 • 2 2	Weight (kg

Pages 4-6: Chemotherapy Cumulative Doses

Most effective/accurate way to code exposure: dose or dose per meter sq?

Enter BSA at start of cycle

No need to list a "stop date" for the chemo

Error checks for units and doses

Need to get accurate BSA at time of new exposures: recommend annual height/weight while on therapy



5 5

77

5 5 5

666

777

888

Total dose,

Incomplete or Partial dose



O gm

5 5 5 5

66666

77777

88888

9 9 9 9 9

O units

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6 . 6 6

7.77

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66606

77707

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777

888

Did this individual undergo any surgical procedures? O No Go to Page 10, Radiation Therapy O Yes (This does not include placement of vascular access devices such as Broviac Catheters, Hickmans, Port-a-Caths, etc.) Include all biopsies identified under general anesthesia. If more than one procedure was done during a surgery, enter each procedure separately. Include ICD-9 code for each procedure performed. 1. Date of First Procedure: 2. Date of Second Procedure: Name of Name of procedure: procedure: (please take from operative report or op note) (please take from operative report or op note) 1st Procedure 2nd Procedure Code MO DAY YR Code MO DAY YR 0000 000000 0000 000000 1111 1111 1111111 2 2 2 2 22222 2222 3333 33333 3333 4444 4 4 4 4444 4 4 4 5 5 5 5 5 5 5 5 5 5 5 6 6 6 6 6666 7777 7777 8 8 8 8 8888 9999 9999 Where was this procedure performed? Where was this procedure performed? This CCSS institution O This CCSS institution Other institution: specify Other institution: specify 3. Date of Third Procedure: 4. Date of Fourth Procedure: Name of Name of procedure: procedure: (please take from operative report or op note) (please take from operative report or op note) 3rd Procedure 4th Procedure ICD-9 Code MO DAY YR Code MO DAY YR 0000 000000 0000 000000 1111 111111 1111 0000002 2 2 2 22222 2222 22222 3 3 3 3 33333 3333 33333 4 4 4 4 4 4 4 4444 444 5 5 5 5 5 5 5 5 5 5 5 6 6 6 6 6 6666 7777 7777 777 8888 8888 9999 9999 Where was this procedure performed? Where was this procedure performed? This CCSS institution O This CCSS institution Other institution: specify Other institution: specify

-7-

Surgical Procedures

Pages 7-9: Surgical Procedures

Recommendations:

- provide space to list the location and name of outside facilities
- no need to give us the ICD-9 code; we will centrally abstract (SJCRH)
- space available for name of procedure, date, location (if other than CCSS center)
- •Specific request to describe extent of surgery for CNS tumors

Radiation Therapy

Did this individual receive radiation therapy?

○ No	→ Go to Page 12, Com	ments Section
O Yes	1	

Please complete a copy of the External Beam or Brachytherapy Data Checklist. Return this checklist and copied records to the Coordinating Center.

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Radiation Therapy

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Pages 10-11: Radiation Therapy

Recommendations:

- Add a recommendation to copy photograph of patient with fields marked if available
- Add space to provide location data and name of radiation facility (if not the CCSS center)
- <u>Need to add space for</u>
 <u>location and name of outside</u>
 <u>facility where XRT received</u>
 will be added to current
 version

PLEASE DO NOT MARK IN THIS AREA

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Pages 12: Comments Section

Other considerations?

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August 24, 2007

BMT question is not
adequate: need to consider
allo / auto / HSCT for support,
etc - will need to get
feedback from BMT groups modification underway

Quality Control: Prior study
did 10% reabstraction.
Discussion of qc limited
because of meeting time and
will continue through email /
other discussions

Contact:

Joe Neglia (Univ of Minnesota) jneglia@umn.edu