Optimizing data collection at a BMT unit

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No disclousure

Optimizing data collection at a BMT unit

Overview:

- Presentation of center
- What was our problem
- What did we do
- How is it going so far
- Local experiences from implementing Med-A day 0
- How we keep track on forms due

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Transplant history in Copenhagen

- First transplant performed April 1971
- Second transplant performed December 1972
- 110-120 first transplants each year

- Myeloablative and non- myeloblative transplants
- Children and adults
- Using BM, PBSC, single and double CBU

- 2000 first transplants
- 1430 myeloablative
- 533 non-myeloablative

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Our center provides data for:

- EBMT - day 0, day +100 and annual
- CIBMTR - day 0, day+100, day+180 and annual
- Different CBB - various
- Local database - day 0, day +100 and annual

- Research center under CIBMTR

- 1000 patients are due to follow up each year.

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What was the problem

- Accurate data collection is essential
- No tradition for systematiclly performing audits

- Most data available - but lack of evaluation
- Physicians not familiar with data collection according to EBMT/CIBMTR

- Preparing for a JACIE accreditation

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What did we do

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Information required for the patient file by day +100, +180 and Annual.

The aim of this tool is to collected correct information on HSCT patients.

Our center collects information for the local database, CIBMTR, EBMT, Donor Registers and Cord Blood Banks.

A number of patients are enrolled in protocols and studies which often requires similar information.

The consulting physician evaluates and documents the following in the patient file:

Status of remission; requires the physicians assessment by blood samples, biopsies, scans (etc.)

GvHD; requires the physicians assessment and diagnosis.

Liver-, lung-, and other complications; requires the physicians assessment and diagnosis.

Karnofsky score and occupational status; informed by the patient at the consultation.

The Data Manager looks up information about:

Take; according to the applicable definitions by reviewing the blood tests and transfusion records in the patients file.

Infections; the clinical microbiology tests are reviewed.

Secondary malignancy; are found in the national pathology database in Denmark.

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Data assed by the consulting physician	Day +100	Day +180	Annual
Karnofsky score	•	•	•
Status of remission	•	•	•
Start of aGvHD, organ involvment, stage and grade	•	•	•
Start of cGvHD organ involvment, grade and overall severity	•	•	•
Liver copmlications	•	•	•
Pulmonary complications	•	•	•
Other complications (TAM, renal failure requireing dialysis, hemorrhage, avascular necrosis, heart failure, diabetes, gonadal dysfunction)	•	•	•
Occupational status		•	•
Date of withdrawal of immunosuppressive agents		•	•

Data collected by the data manager	Day +100	Day +180	Annual
Take	•		
Infection	•	•	•
Secondary malignancy	•	•	•

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Akut GvHD
Grading and Staging:

Stage	Skin	Liver (billirubin)	Gut/GI (diarrhea)*
1	< 25%	> 34 µmol/l - 2-3 mg/dl	> 500 ml (> 283 ml/m²)
2	> 25-50%	> 52 µmol/l – 3-6 mg/dl	> 1000 ml (> 555 ml/m²)
3	> 50-100%	> 103µmol/l – 6-15 mg/dl	> 1500 ml (> 833 ml/m²)
4	+ bullous formation	> 255 µmol/l - > 15 mg/dl	+ severe abdominal pain ± ileus

* Diarrhea are related to surface for patients < 40 kg.
Upper GI GvHD verified by biopsy = GI stadium ≥ 1.

Grading:

Grade I	Skin 1-2	Liver 0 and Gut 0
Grade II	Skin 1-3	Liver 1 and/or Gut 1
Grade III	Skin 2-3	Liver 2-3 and/or Gut 2-3. And affected general condition.
Grade IV	Skin 2-4	Liver 2-4 and/or Gut 2-4. And severe affected general condition.

Body Area	Percent	Total Percentage
Each Arm	9%	18%
Each Leg	18%	36%
Chest & Abdomen	18%	18%
Back	18%	18%
Head	9%	9%
Pubis	1%	1%

VOD (a.m. Jones)
Billirubin > 34 mmol/l and at least two of the following a: hepatomegalt. b: ascites. c: weight gain > 5 % before day 21

Chronic GvHD
Report **"limited"** if chronic GVHD includes only localized skin involvement and/or liver dysfunction.
Report **"extensive"** if **any** of the following symptoms are attributed to chronic GVHD:
Generalized skin involvement and/or liver dysfunction
Liver histology showing chronic aggressive hepatitis, bridging necrosis, or cirrhosis
Involvement of the eye
Involvement of the salivary glands or oral mucous membranes
Involvement of any other target organ

Overall severity of chronic GVHD
Currently there are no specific criteria for the severity of chronic GVHD. This subjective assessment should be reported as documented by the physician using the guidelines below:
Mild - signs and symptoms of chronic GVHD do not interfere substantially with function and do not progress once appropriately treated with local therapy or standard systemic therapy (corticosteroids and/or CyA/ FK 506/MMF/Sirolimus).
Moderate - signs and symptoms of chronic GVHD interfere somewhat with function despite appropriate therapy or are progressive through first line systemic therapy (corticosteroids and/or CyA/FK 506/MMF/Sirolimus).
Severe - signs and symptoms of chronic GVHD limit function substantially despite appropriate therapy or are progressive through second line therapy

Karnofsky	Performance	Lansky
Normal. No complaints. No evidence of disease.	100	Fully active, normal
Able to carry on normal activity. Minor signs or symptoms of disease.	90	Minor restrictions with strenuous physical activity
Normal activity with effort. Some signs or symptoms of disease.	80	Active, but gets tired more quickly
Cares for self. Unable to carry on normal activity or to do active work.	70	Both greater restriction of, and less time spent in, active play
Requires occasional assistance, but is able to care for most of personal needs.	60	Up and around, but minimal active play; keeps busy with quieter activities
Requires considerable assistance and frequent medical care.	50	Lying around much of the day, but gets dressed; no active play; participates in all quiet play and activities
Disabled. Requires special care and assistance.	40	Mostly in bed; participates in quiet activities
Severely disabled. Hospital admission is indicated although death is not imminent.	30	Stuck in bed; needs help even for quiet play
Hospitalization necessary. Very sick, active supportive treatment necessary.	20	Often sleeping; play is entirely limited to very passive activities
Moribund; fatal processes progressing rapidly.	10	Does not play nor get out of bed
Dead	0	Unresponsive

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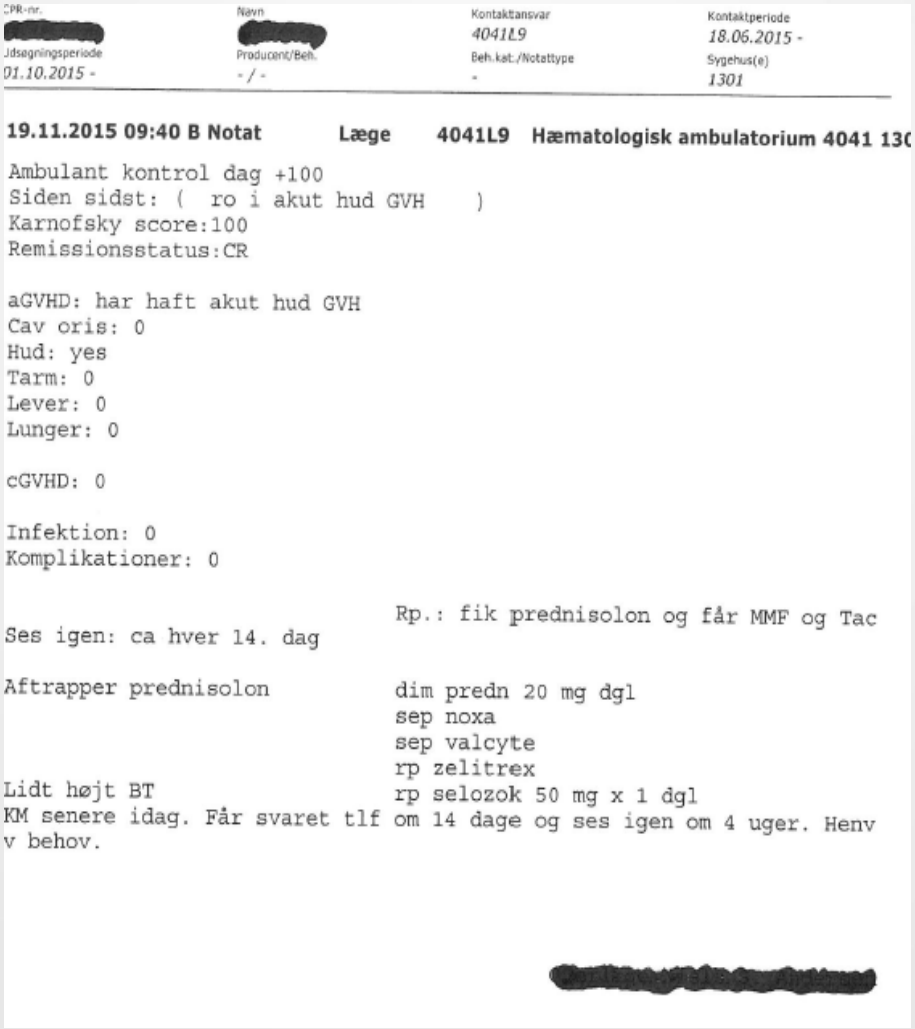
Standard note day +100



CPR-nr.	Navn	Kontaktansvar	Kontaktperiode
[redacted]	[redacted]	4041L9	18.06.2015 -
Udsøgningsperiode	Producent/Beh.	Beh.kat./Notattype	Sygehus(e)
01.10.2015 -	- / -	-	1301

19.11.2015 09:40 B Notat Læge 4041L9 Hæmatologisk ambulatorium 4041 13C

Ambulant kontrol dag +100
Siden sidst: (ro i akut hud GVH)
Karnofsky score:100
Remissionsstatus:CR

aGVHD: har haft akut hud GVH
Cav oris: 0
Hud: yes
Tarm: 0
Lever: 0
Lunger: 0

cGVHD: 0

Infektion: 0
Komplikationer: 0

Rp.: fik prednisolon og får MMF og Tac

Ses igen: ca hver 14. dag

Aftrapper prednisolon

dim predn 20 mg dgl
sep noxa
sep valcyte
rp zelitrex
rp selozok 50 mg x 1 dgl

Lidt højt BT
KM senere idag. Får svaret tlf om 14 dage og ses igen om 4 uger. Henv v behov.

[redacted]

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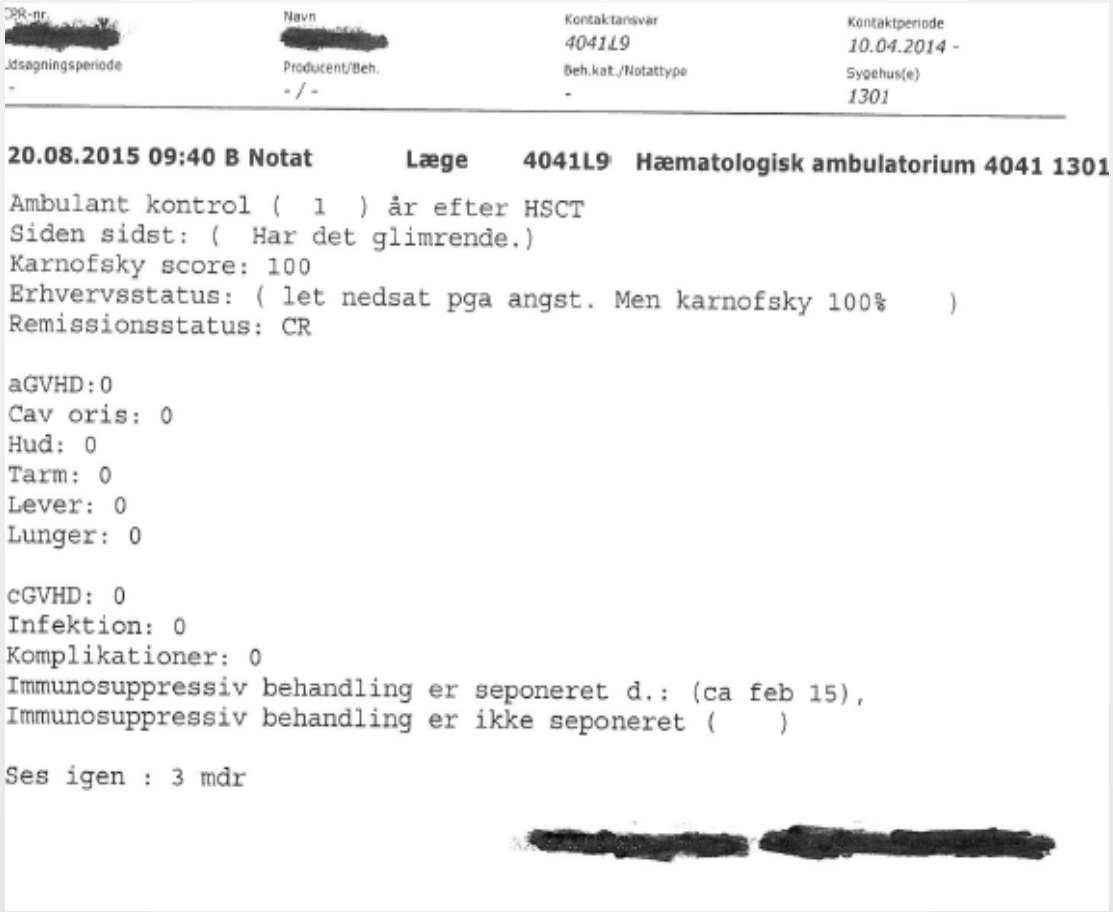
Standard note annual



CPR-nr. [redacted]
Udsøgningsperiode
-

Navn [redacted]
Producent/Beh.
- / -

Kontaktansvar
4041L9
Beh.kat./Notattype
-

Kontaktperiode
10.04.2014 -
Sygehus(e)
1301

20.08.2015 09:40 B Notat Læge 4041L9 Hæmatologisk ambulatorium 4041 1301

Ambulant kontrol (1) år efter HSCT
Siden sidst: (Har det glimrende.)
Karnofsky score: 100
Erhvervsstatus: (let nedsat pga angst. Men karnofsky 100%)
Remissionsstatus: CR

aGVHD:0
Cav oris: 0
Hud: 0
Tarm: 0
Lever: 0
Lunger: 0

cGVHD: 0
Infektion: 0
Komplikationer: 0
Immunosuppressiv behandling er seponeret d.: (ca feb 15),
Immunosuppressiv behandling er ikke seponeret ( )

Ses igen : 3 mdr

[redacted]

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How are we doing so far

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The results from the first day +100 audit:

- 44% had all requested data available
- 44% had KF available
- 56% had status of remission available
- 89% had GvHD status available

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The results from the first day +180 audit:

- 27% had all requested data available
- 64% had KF available
- 36% had status of remission available
- 55% had GvHD status available
- 45% had status of current or most recent work status available

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The results from the second day +100 audit:

- 31% had all requested data available
- 50% had KF available
- 63% had status of remission available
- 63% had GvHD status available

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The results from the second day +180 audit:

- 50% had all requested data available
- 50% had KF available
- 75% had status of remission available
- 75% had GvHD status available
- 75% had status of current or most recent work status available

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The results from the first annually visit:

- 42% had all requested data available
- 46% had KF available
- 58% had status of remission available
- 62% had GvHD status available
- 54% had status of current or most recent work status available

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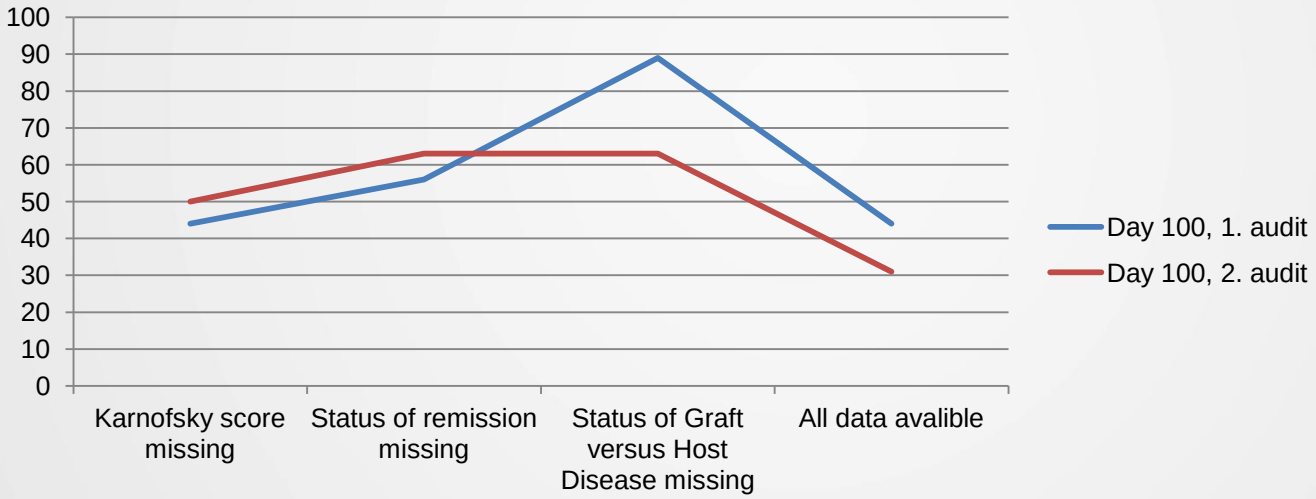
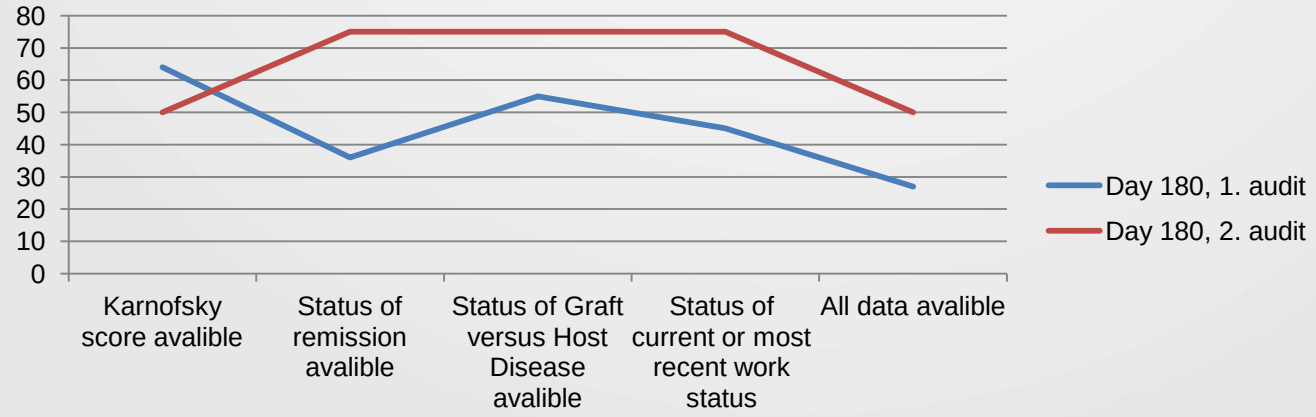
Comparing audit results:





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Local experiences from implementing Med-A day 0

How we prepare for data collection

- Create a folder containing information with name, date of birth, diagnose, date of diagnose, date and type of transplant, donor information
- Paper copy of Med-A or Med-B and disease specific form

Collecting data starts when conditioning regime has started

- Using patient file for informations on pre transplant condition, donor and graft information and conditioning regime.
- Using referring file for information on primary disease and treatment.

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How do we keep track on what to do when

Data are requested:

- EBMT – day 0, day +100 and annual
- CIBMTR – day 0, day+100, day+180 and annual
- Different CBB - various
- Local database – day 0, day +100 and annual

- Various guidelines for follow up

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In order to keep track on what to do and when to do it - we created our own folder system, that is fairly staright forward and easy to use

- Three different sheets; +100, +180 and annual follow up
- Prefilled with UPN, CRID, name, date of birth, diagnose, date of transplant, data and which form due

- One folder containing the sheets; +100 and +180 follow up
- One folder containing the sheet; annaul follow up

- Stored in order of month and due date

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THANK YOU FOR LISTENING

Questions?

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