CIC: ..... Hospital UPN: ..... Patient UIC ..... HSCT Date: .....
yyyy - mm - dd

HSCT - Minimum Essential Data - A

REGISTRATION - DAY 0

Centre Identification

EBMT Code (CIC): ..... Contact person: .....

Hospital: ..... Unit: ..... Email: .....

Patient Data

Date of this report: ..... First transplant for this patient?: ☐ Yes ☐ No
yyyy - mm - dd

Patient following national / international study / trial:

☐ No ☐ Yes: Name of study / trial ..... ☐ Unknown

Hospital Unique Patient Number or Code (UPN) .....

Compulsory, registrations will not be accepted without this item.

All transplants performed in the same patient must be registered with the same patient identification number or code as this belongs to the patient and <u>not</u> to the transplant.

Initials: ..... _ ..... (first name(s) _family name(s))

Date of birth: ..... Sex: ☐ Male ☐ Female
yyyy - mm - dd ***(at birth)***

Primary Disease Diagnosis

Date of initial diagnosis: .....
yyyy - mm - dd

PRIMARY DISEASE DIAGNOSIS *(CHECK THE DISEASE FOR WHICH THIS TRANSPLANT WAS PERFORMED)*

☐ Acute Leukaemia ☐ Acute Myelogenous Leukaemia (AML) related Precursor Neoplasms ☐ Precursor Lymphoid Neoplasms (old ALL) ☐ Therapy related myeloid neoplasms (old Secondary Acute Leukaemia) ☐ Chronic Leukaemia ☐ Chronic Myeloid Leukaemia (CML) ☐ Chronic Lymphocytic Leukaemia (CLL) ☐ Lymphoma ☐ Non Hodgkin ☐ Hodgkin's Disease	☐ Myeloma/Plasma cell disorder ☐ Solid Tumour ☐ Myelodysplastic syndromes / Myeloproliferative neoplasm ☐ MDS ☐ MDS/MPN ☐ Myeloproliferative neoplasm ☐ Bone marrow failure including Aplastic anaemia ☐ Inherited disorders ☐ Primary immune deficiencies ☐ Metabolic disorders	☐ Histiocytic disorders ☐ Autoimmune disease ☐ Juvenile Idiopathic Arthritis ☐ Multiple Sclerosis ☐ Systemic Lupus ☐ Systemic Sclerosis ☐ Haemoglobinopathy

☐ Other diagnosis, specify: _____

CIC: _____ Hospital UPN: _____ Patient UIC _____ HSCT Date: _____
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MYELODYSPLASTIC SYNDROME (MDS)(main disease code 6)

Disease

Date of Initial Diagnosis: _____
yyyy - mm - dd

Select only one

WHO Classification at diagnosis:

- ☐ Refractory anaemia *(without ring sideroblasts) (RA)*
- ☐ RA with ring sideroblasts (RARS)
- ☐ MDS associated with isolated del(5q)
- ☐ Refractory cytopenia with multilineage dysplasia (RCMD)
- ☐ RCMD with ringed sideroblasts (RCMD-RS)
- ☐ RA with excess of blasts-1 (RAEB-1)
- ☐ RA with excess of blasts-2 (RAEB-2)
- ☐ Childhood myelodysplastic syndrome *(Refractory cytopenia of childhood (RCC))*
- ☐ MDS Unclassifiable (MDS-U)

Secondary Origin?

Therapy related MDS:
(Secondary origin)

- ☐ Yes : Disease related to prior exposure to therapeutic drugs or radiation
- ☐ No
- ☐ Unknown

IF THE PATIENT HAS RECEIVED AN ALLOGRAFT PRIOR TO THE DIAGNOSIS OF MDS, ANSWER THE FOLLOWING QUESTION

Is this a donor cell leukaemia ☐ No ☐ Yes ☐ Not evaluated

CIC: ---------- Hospital UPN: ---------- Patient UIC ---------- HSCT Date: ----------
yyyy - mm - dd

MYELODYSPLASTIC SYNDROME (MDS)(main disease code 6)

Chromosome Analysis at Diagnosis

Chromosome analysis at diagnosis (All methods including FISH)

☐ Normal ☐ Abnormal ☐ Not done or failed ☐ Unknown

If abnormal:

Complex kariotype: ☐ No ☐ Yes ☐ Unknown
(3 or more abnormalities)

You can transcribe the complete karyotype: ----------

OR

Indicate below those abnormalities that have been evaluated and whether they were Absent or Present:

del Y (-Y)	☐ Absent ☐ Present ☐ Not evaluated
abn 5 type *Fill only if abn 5 is Present*	☐ Absent ☐ Present ☐ Not evaluated
del5q (5q-)	☐ Absent ☐ Present ☐ Not evaluated
Other abn 5, specify _ _ _ _ _ _ _ _	☐ Absent ☐ Present ☐ Not evaluated
del 20q (20q-)	☐ Absent ☐ Present ☐ Not evaluated
abn 7 type *Fill only if abn 7 is Present:*	☐ Absent ☐ Present ☐ Not evaluated
del 7q (7q-)	☐ Absent ☐ Present ☐ Not evaluated
Other abn 7, specify	☐ Absent ☐ Present ☐ Not evaluated
abn 3 type *Fill only if abn 3 is Present:*	☐ Absent ☐ Present ☐ Not evaluated
inv(3)	☐ Absent ☐ Present ☐ Not evaluated
t(3q;3q)	☐ Absent ☐ Present ☐ Not evaluated
del(3q)	☐ Absent ☐ Present ☐ Not evaluated
Other abn 3, specify	☐ Absent ☐ Present ☐ Not evaluated
del11q	☐ Absent ☐ Present ☐ Not evaluated
trisomy 8	☐ Absent ☐ Present ☐ Not evaluated
trisomy 19	☐ Absent ☐ Present ☐ Not evaluated
i(17q)	☐ Absent ☐ Present ☐ Not evaluated
Other, specify	☐ Absent ☐ Present ☐ Not evaluated

Molecular Markers at Diagnosis

Marker analysis at diagnosis

☐ Not evaluated
☐ Evaluated: Absent
☐ Evaluated: Present
☐ Unknown

*If you are entering an **AML with myelodyplasia related changes,** return to the Acute Leukaemia to continue*

MYELODYSPLASTIC SYNDROME (MDS)(main disease code 6)

Status at HSCT

Date of this HSCT: ----------
yyyy - mm - dd

Select only one

WHO Classification at HSCT:

- ☐ Refractory anaemia (RA) (without ring sideroblasts)
- ☐ RA with ring sideroblasts (RARS)
- ☐ MDS associated with isolated del(5q)
- ☐ Refractory cytopenia with multilineage dysplasia (RCMD)
- ☐ RCMD with ringed sideroblasts (RCMD-RS)
- ☐ RA with excess of blasts-1 (RAEB-1)
- ☐ RA with excess of blasts-2 (RAEB-2)
- ☐ Childhood myelodysplastic syndrome (Refractory cytopenia of childhood (RCC))
- ☐ MDS Unclassifiable (MDS-U)

STATUS	**NUMBER**
Treated with chemotherapy: ☐ Primary refractory phase (no change)	
☐ Complete remission (CR)	☐ 1st ☐ 2nd ☐ 3rd or higher
☐ Improvement but no CR	
☐ Relapse (after CR)	☐ 1st ☐ 2nd ☐ 3rd or higher
☐ Progression/worse ☐ Never treated (Supportive care or treatment without chemotherapy)	

CIC: ..... Hospital UPN: ..... Patient UIC ..... HSCT Date: .....
yyyy - mm - dd

HSCT

Performance score system used ☐ Karnofsky ☐ Lansky

Score ☐ 10 ☐ 20 ☐ 30 ☐ 40 ☐ 50 ☐ 60 ☐ 70 ☐ 80 ☐ 90 ☐ 100

Weight (kg): ..... **Height (cm):** .....

Comorbidity Index

Sorror et al., Blood, 2005 Oct 15; 106(8): 2912-2919: *http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1895304/*

Was there any ***clinically significant*** co-existing disease or organ impairment at time of patient assessment just prior to the preparative regimen?

☐ No ☐ Yes

Comorbidity	Definitions	No	Yes	N/E
Solid tumour, previously present	Treated at any time point in the patient's past history, excluding non-melanoma skin cancer Indicate type	☐	☐	☐
Infammatory bowel disease	Crohn's disease or ulcerative colitis	☐	☐	☐
Rheumatologic	SLE, RA, polymyositis, mixed CTD, or polymyalgia rheumatica	☐	☐	☐
Infection	Requiring continuation of antimicrobial treatment after day 0	☐	☐	☐
Diabetes	Requiring treatment with insulin or oral hypoglycaemics but not diet alone	☐	☐	☐
Renal: moderate/severe	Serum creatinine > 2 mg/dL or >177 µmol/L, on dialysis, or prior renal transplantation	☐	☐	☐
Hepatic: mild	Chronic hepatitis, bilirubin between Upper Limit Normal (ULN) and 1.5 x the ULN, or AST/ALT between ULN and 2.5 × ULN	☐	☐	☐
moderate/ severe	Liver cirrhosis, bilirubin greater than 1.5 × ULN, or AST/ALT greater than 2.5 × ULN	☐	☐	☐
Arrhythmia	Atrial fibrillation or flutter, sick sinus syndrome, or ventricular arrhythmias	☐	☐	☐
Cardiac	Coronary artery disease, congestive heart failure, myocardial infarction, EF ≤ 50%, or shortening fraction in children (<28%)	☐	☐	☐
Cerebrovascular disease	Transient ischemic attack or cerebrovascular accident	☐	☐	☐
Heart valve disease	Except mitral valve prolapse	☐	☐	☐
Pulmonary: moderate	DLco and/or FEV1 66-80% or dyspnoea on slight activity	☐	☐	☐
severe	DLco and/or FEV1 ≤ 65% or dyspnoea at rest or requiring oxygen	☐	☐	☐
Obesity	Patients with a body mass index > 35 kg/m2	☐	☐	☐
Peptic ulcer	Requiring treatment	☐	☐	☐
Psychiatric disturbance	Depression or anxiety requiring psychiatric consultation or treatment	☐	☐	☐

Were there any other major clinical abnormalities prior to the preparative regimen? Specify.....

CIC: _____ Hospital UPN: _____ Patient UIC _____ HSCT Date: _____
yyyy - mm - dd

Type of HSCT (Allogeneic)

☐ **Allogeneic**

Patient CMV status ☐ Negative ☐ Positive ☐ Not evaluated ☐ Unknown

Multiple donors *(including multiple CB units)* ☐ No ☐ Yes: Number of donors _____

Donor 1

HLA MATCH TYPE *(DONOR RELATION WITH PATIENT)*

☐ HLA - Identical sibling *(may include non-monozygotic twin)*
☐ Syngeneic *(monozygotic twin)*
☐ HLA - Matched other relative
☐ HLA - Mismatched relative: Degree of mismatch ☐ 1 HLA locus mismatch ☐ >=2 HLA loci mismatch

Donor ID given by the centre _____

HLA MISMATCHES BETWEEN DONOR AND PATIENT
(Mismatched relatives only)

Complete number of mismatches inside each box

A	B	C	DRB1	DQB1	DPB1	
☐	☐	☐	☐	☐	☐	Antigenic
☐	☐	☐	☐	☐	☐	Allelic

0=match; 1=one mismatch; 2=2 mismatches; N/E=not evaluated

☐ Unrelated donor

ION code of the Donor Registry or CB Bank _____

BMDW code of the Donor Registry or CB Bank *(If ION code is unknown)* *(up to 4 characters)* _____

Name of Donor Registry/ CB Bank *(If any of the above codes is unknown)* _____

Donor centre name *(if applicable, optional)* _____

Donor ID given by the Donor Registry or the CB Bank listed above _____

Patient ID given by the Donor Registry or the CB Bank listed above _____

⇨ Please enter the LABORATORY RESULTS WITH HLA TYPING into the database

Donor information

Date of birth _____ *yyyy - mm - dd* OR Age at time of donation *(if date of birth not provided)* _____ _____ *month(s)*

Donor Sex ***(at birth)*** ☐ Male ☐ Female

Donor CMV status ☐ Negative ☐ Positive ☐ Not evaluated ☐ Unknown

Did this donor provide more than one stem cell product

☐ No - *(please fill "Donor 1 – Product Number 1" on next page*
☐ Yes: Number of different stem cell products infused from this donor _____
(If 2 products e.g. BM PB, please fill "Donor 1 – Product Number 1 AND 2" on next page)

Donor 1 - Product Number 1

If more than one stem cell product, this is the FIRST product infused from this donor

Source of Stem Cells for **this product** , select only **one**

☐ Bone marrow ☐ Peripheral blood

☐ Cord blood ☐ Other: ----------

Graft manipulation ex-vivo of this product including T-cell depletion
other than for RBC removal or volume reduction

☐ No

☐ Yes Negative: ☐ No ☐ Yes:

☐ *T-cell (CD3+) depletion (do not use for "Campath in bag")*
☐ T-cell receptor αβ depletion
☐ B-cell depletion (CD19+) by MoAB
☐ NK cell depletion by MoAB
☐ Other ----------

Positive: ☐ No ☐ Yes
☐ CD34+ enrichment

Genetic manipulation ☐ No ☐ Yes

⇨ Please enter the LABORATORY RESULTS WITH HLA TYPING into the database

Donor 1 - Product Number 2

If more than one stem cell product, this is the SECOND product infused from this donor

Source of Stem Cells for **this product** , select only **one**

☐ Bone marrow ☐ Peripheral blood

☐ Cord blood ☐ Other: ----------

Graft manipulation ex-vivo of this product including T-cell depletion
other than for RBC removal or volume reduction

☐ No

☐ Yes Negative: ☐ No ☐ Yes:

☐ *T-cell (CD3+) depletion (do not use for "Campath in bag")*
☐ T-cell receptor αβ depletion
☐ B-cell depletion (CD19+) by MoAB
☐ NK cell depletion by MoAB
☐ Other ----------

Positive: ☐ No ☐ Yes
☐ CD34+ enrichment

Genetic manipulation ☐ No ☐ Yes

⇨ Please enter the LABORATORY RESULTS WITH HLA TYPING into the database

CIC: ..... Hospital UPN: ..... Patient UIC ..... HSCT Date: .....
yyyy - mm - dd

Donor 2

HLA MATCH TYPE *(DONOR RELATION WITH PATIENT)*

- ☐ HLA - Identical sibling *(may include non-monozygotic twin)*
- ☐ Syngeneic *(monozygotic twin)*
- ☐ HLA - Matched other relative
- ☐ HLA - Mismatched relative Degree of mismatch ☐ 1 HLA locus mismatch ☐ >=2 HLA loci mismatch

.....

HLA MISMATCHES BETWEEN DONOR AND PATIENT
(Mismatched relatives only)

Complete number of mismatches inside each box

A	B	C	DRB1	DQB1	DPB1	
☐	☐	☐	☐	☐	☐	Antigenic
☐	☐	☐	☐	☐	☐	Allelic

0=match; 1=one mismatch; 2=2 mismatches; N/E=not evaluated

☐ Unrelated donor

ION code of the Donor Registry or CB Bank .....

BMDW code of the Donor Registry or CB Bank *(If ION code is unknown)* *(up to 4 characters)* .....

Name of Donor Registry/ CB Bank *(If any of the above codes is unknown)* .....

Donor centre name *(if applicable, optional)* .....

Donor ID given by the Donor Registry or the CB Bank listed above .....

Patient ID given by the Donor Registry or the CB Bank listed above .....

⇨ **Please enter the LABORATORY RESULTS WITH HLA TYPING into the database**

Donor information

Date of birth ..... OR Age at time of donation *(if date of birth not provided)*
yyyy - mm - dd
.....*year(s)* .....*month(s)*

Donor Sex ***(at birth)*** ☐ Male ☐ Female

Donor CMV status ☐ Negative ☐ Positive ☐ Not evaluated ☐ Unknown

Did this donor provide more than one stem cell product

- ☐ No *(please fill "Donor 1 – Product Number 1" on next page*
- ☐ Yes: Number of different stem cell products infused from this donor .....

(If 2 products e.g. BM PB, please fill "Donor 1 – Product Number 1 AND 2" on next page)

Donor 2 - Product Number 1

If more than one stem cell product, this is the FIRST product infused from this donor

Source of Stem Cells for this product, select only one

☐ Bone marrow ☐ Peripheral blood

☐ Cord blood ☐ Other source ----------

Graft manipulation ex-vivo including T-Cell depletion

other than for RBC removal or volume reduction

☐ No

☐ Yes Negative: ☐ No ☐ Yes:

☐ *T-cell (CD3+) depletion (do not use for "Campathbag")*
☐ T-cell receptor αβ depletion
☐ B-cell depletion (CD19+) by MoAB
☐ NK cell depletion by MoAB
☐ Other ----------

Positive: ☐ No ☐ Yes

☐ CD34+ enrichment

Genetic manipulation ☐ No ☐ Yes

⇨ Please enter the LABORATORY RESULTS WITH HLA TYPING into the database

Donor 2 - Product Number 2

If more than one stem cell product, this is the SECOND product infused from this donor

Source of Stem Cells for this product, select only one

☐ Bone marrow ☐ Peripheral blood

☐ Cord blood ☐ Other source ----------

Graft manipulation ex-vivo including T-Cell depletion

other than for RBC removal or volume reduction

☐ No

☐ Yes Negative: ☐ No ☐ Yes:

☐ *T-cell (CD3+) depletion (do not use for "Campathbag")*
☐ T-cell receptor αβ depletion
☐ B-cell depletion (CD19+) by MoAB
☐ NK cell depletion by MoAB
☐ Other ----------

Positive: ☐ No ☐ Yes

☐ CD34+ enrichment

Genetic manipulation ☐ No ☐ Yes

⇨ Please enter the LABORATORY RESULTS WITH HLA TYPING into the database

HSCT (Continued)

Chronological number of HSCT for this patient? | |

If >1, date of last HSCT before this one _____
yyyy - mm - dd

If >1, type of last HSCT before this one ☐ Allo ☐ Auto

If >1 and Allograft, Was the same donor used for all prior and current HSCTs? ☐ No ☐ Yes

If >1, was last HSCT peformed at another institution? ☐ No ☐ Yes: CIC if known _____

Name of the institution _____

City _____

⇨ If >1, please submit an Annual follow up form before proceeding, **giving the date of the subsequent transplant as the date of last contact**
(This is so we can capture relapse data and other events between transplants).

HSCT part of a planned multiple (sequential) graft protocol *(program)**?***

☐ No ☐ Yes

Preparative Regimen

Preparative (conditioning) **regimen given?**

☐ No *(Usually Paed Inherited Disorders only) Go to GvHD Prophylaxis*

☐ Yes

Was this intended to be myeloablative? *(allo only)*

☐ Yes ☐ No: Reason

☐ Age of recipient
☐ Comorbid conditions
☐ Prior HSCT
☐ Protocol driven
☐ Other, specify _____

Drugs ☐ No ☐ Yes ☐ Unknown

(include any active agent be it chemo, monoclonal antibody, polyclonal antibody, serotherapy, etc.)

Specification and dose of the preparative regimen

TOTAL PRESCRIBED CUMULATIVE DOSE*

as per protocol:

DRUG (given before day 0)	DOSE	UNITS		
☐ Ara-C (cytarabine)		☐ mg/m2	☐ mg/kg	
☐ ALG, ATG (ALS/ ATS) Animal origin: ☐ Horse ☐ Rabbit ☐ Other, specify		☐ mg/m2	☐ mg/kg	
☐ Bleomycin		☐ mg/m2	☐ mg/kg	
☐ Busulfan ☐ Oral ☐ IV ☐ Both		☐ mg/m2	☐ mg/kg	☐ mg x hr/L ☐ micromol x min/L ☐ mg x min/mL
☐ BCNU		☐ mg/m2	☐ mg/kg	
☐ Bexxar (radio labelled MoAB)		☐ mCi	☐ MBq	
☐ CCNU		☐ mg/m2	☐ mg/kg	
☐ Campath (AntiCD 52)		☐ mg/m2	☐ mg/kg	
☐ Carboplatin		☐ mg/m2	☐ mg/kg	☐ mg x hr/L ☐ micromol x min/L ☐ mg x min/mL
☐ Cisplatin		☐ mg/m2	☐ mg/kg	
☐ Clofarabine		☐ mg/m2	☐ mg/kg	
☐ Corticosteroids		☐ mg/m2	☐ mg/kg	
☐ Cyclophosphamide		☐ mg/m2	☐ mg/kg	
☐ Daunorubicin		☐ mg/m2	☐ mg/kg	
☐ Doxorubicin (adriamycine)		☐ mg/m2	☐ mg/kg	
☐ Epirubicin		☐ mg/m2	☐ mg/kg	
☐ Etoposide (VP16)		☐ mg/m2	☐ mg/kg	
☐ Fludarabine		☐ mg/m2	☐ mg/kg	
☐ Gemtuzumab		☐ mg/m2	☐ mg/kg	
☐ Idarubicin		☐ mg/m2	☐ mg/kg	
☐ Ifosfamide		☐ mg/m2	☐ mg/kg	
☐ Imatinib mesylate		☐ mg/m2	☐ mg/kg	
☐ Melphalan		☐ mg/m2	☐ mg/kg	
☐ Mitoxantrone		☐ mg/m2	☐ mg/kg	
☐ Paclitaxel		☐ mg/m2	☐ mg/kg	
☐ Rituximab (mabthera, antiCD20)		☐ mg/m2	☐ mg/kg	
☐ Teniposide		☐ mg/m2	☐ mg/kg	
☐ Thiotepa		☐ mg/m2	☐ mg/kg	
☐ Treosulphan		☐ mg/m2	☐ mg/kg	
☐ Zevalin (radiolabelled MoAB)		☐ mCi	☐ MBq	
☐ Other radiolabelled MoAB Specify		☐ mCi	☐ MBq	
☐ Other MoAB, specify		☐ mg/m2	☐ mg/kg	
☐ Other, specify		☐ mg/m2	☐ mg/kg	

**Report the total prescribed cumulative dose as per protocol. Multiply daily dose in mg/kg or mg/m² by the number of days; e.g. for Busulfan given 4mg/kg daily for 4days, total dose to report is 16mg/kg*

**AUC = Area under the curve

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Total Body Irradiation (TBI) ☐ No ☐ Yes : Total prescribed radiation dose as per protocol ..... Gy

Number of fractions ..... over ..... radiation days

TLI, TNI, TAI ☐ No ☐ Yes : Total prescribed radiation dose as per protocol ..... Gy

(lymphoid, nodal, abdominal)

GvHD prophylaxis or preventive treatment *(Allografts only)*

☐ No ☐ Yes

If Yes: ☐ Drugs (Immunosuppressive chemo)

- ☐ ALG, ALS, ATG, ATS : *(given after day 0)* Animal origin: ☐ Horse ☐ Rabbit ☐ Other, specify .....
- ☐ Anti CD25*(MoAB in vivo)*
- ☐ Campath *(MoAB in vivo; can be "in the bag")*
- ☐ Systemic corticosteroids
- ☐ Cyclosporine
- ☐ Cyclophosphamide *(given after day 0)*
- ☐ Etanercept *(MoAB in vivo)*
- ☐ FK 506 *(Tacrolimus, Prograf)*
- ☐ Infliximab *(MoAB in vivo)*
- ☐ Methotrexate
- ☐ Mycophenolate *(MMF)*
- ☐ Sirolimus
- ☐ Other monoclonal antibody *(in vivo)* , specify .....
- ☐ Other agent (in vivo), specify.....

☐ Extracorporeal photopheresis (ECP)

☐ Other, specify .....

Survival Status

Survival Status on date of HSCT

☐ Alive ☐ Dead

☐ Patient died between administration of the preparative regimen and date of HSCT

Main Cause of Death *(check only one main cause):*

- ☐ Relapse or Progression/Persistent disease
- ☐ HSCT Related Cause
- ☐ Unknown
- ☐ Other .....

Contributory Cause of Death *(check as many as appropriate):*

- ☐ GVHD
- ☐ Interstitial pneumonitis
- ☐ Pulmonary toxicity
- ☐ Infection:
  - ☐ bacterial
  - ☐ viral
  - ☐ fungal
  - ☐ parasitic
  - ☐ Unknown
- ☐ Rejection/Poor graft function
- ☐ History of severe Veno occlusive disorder (VOD)
- ☐ Haemorrhage
- ☐ Cardiac toxicity
- ☐ Central nervous system (CNS) toxicity
- ☐ Gastrointestinal (GI) toxicity
- ☐ Skin toxicity
- ☐ Renal failure
- ☐ Multiple organ failure
- ☐ Other, specify .....