NATIONAL COLLABORATING CENTRE FOR CANCER (NCC-C)

Myeloma

First Guideline Development Group (GDG) meeting
27th & 28th March 2014
Board Room, NCC-C, Park House, Greyfriars Road, Cardiff

GROUP MEMBERSHIP & ACTION LIST

GDG Members	
Curly Morris (CM)	Monica Morris (MM)
Guy Pratt (GP)	Sam Ahmedzai (SA)
John Snowden (JS)	Nicola Montacute (NMo)
Matthew Jenner (MJ)	Jane Woodward (JW)
Matthew Streetly (MS)	Lesley Roberts (LR)
Hamdi Sati (HS)	Alan Chant (ACh)
Nicola Mulholland (NM)	Andrea Guy (AG)
NCC-C staff	
John Graham (JG)	Kim Lewis (KL)
Angela Bennett (AB)	Elise Hasler (EH)
Dr Nathan Bromham (NB)	Angharad Morgan (AM)
Dr Andrew Champion (AC) *(Day 1 only)*	James Hawkins (JH)
Matthew Prettyjohns (MP) *(Day 1 only)*	Coral McCarthy (CM) *(Observer Day 2 only)*
NICE staff	
Katie Perryman Ford (KPF)	Erin Whittingham (EW)

REPORTS OF DISCUSSIONS AT THE MEETING

1. Introductions

CM welcomed everyone to the 1st meeting of the Myeloma GDG.

2. Declarations of Interest

The following declarations of interest were declared prior to the meeting:

- CM declared that he has received reimbursement of travel and subsistence expenses, and registration fee to attend the American Society for Haematology Meeting in Atlanta. This interest was categorised as personal pecuniary, non-specific meaning that CM can declare and participate in discussion of all guideline topics, as expenses not beyond reasonable amounts.
- CM declared that he has received financial support from Celgene paid to Altnagelvin Haematology Laboratory Trust Funds to attend the International Myeloma Workshop in Kyoto, Japan. This interest was categorised as personal pecuniary, non-specific meaning that CM can participate in discussion of all guideline topics, as expenses not beyond reasonable amounts.
- CM declared that he has received financial support from Mundi Pharma paid to Altnagelvin Haematology Laboratory Trust Funds to attend the European Blood and Marrow Transplant Meeting in London. This interest was categorised as personal pecuniary, non-specific meaning that CM can participate in discussion of all guideline topics, as expenses not beyond reasonable amounts.

- CM declared that he is a member of the trial management group and involved in designing the trial protocol for the Myeloma X trial (phase III on the role of a second autologous stem cell transplant in patients with relapsed myeloma following high does rate chemotherapy and autologous stem cell rescue). Trial is funded by CRUK. This interest was categorised as non-personal pecuniary, specific, meaning that CM can participate in discussion of all guidelines topics as the research was not funded by the healthcare industry.
- CM declared that he was principle investigator and involved in designing the trial protocol for an Irish Clinical Oncology Research Group (ICORG) sponsored phase II trial of Bortezomib, Adriamycin and Dexamethasone (PAD) in patients with relapsed and refractory myeloma from 2006-2010. Costs and free drug from Jansen Cilag. This interest was categorised as non-personal pecuniary, (specific/non-specific TBC once clinical questions have been finalised), meaning that CM must declare and withdraw from discussion of any topics which include PAD as an intervention until 12 months after publication of the results.
- GP declared that he receives an annual payment from the Binding Site Ltd for being a member of their advisory board and providing general clinical advice. This involves overseeing, as chief investigator, a study recruiting normal blood donors from within the company for control samples. This interest was categorised as personal pecuniary, specific meaning that GP must declare and withdraw from discussion of any topics which include serum free light chain assays as an intervention.
- GP declared that he has received an honorarium from Celgene for chairing a meeting on general myeloma issues in Feb 2013. This interest was classified as personal pecuniary, non-specific meaning that GP can participate in discussion of all guideline topics, as expenses not beyond reasonable amounts.
- GP declared that he has received an honorarium from Janssen for a presentation on Waldenstroms in. This interest was declared as personal pecuniary, non specific meaning that GP can participate in discussion of all guideline topic as Waldenstroms is not being investigated by the guideline.
- GP declared that he has received support for travel, accommodation and subsistence expenses from Binding Site Ltd to attend an educational meeting in Japan. This interest was classified as personal pecuniary, non-specific meaning that GP can participate in discussion of all guideline topics, as expenses not beyond reasonable amounts.
- GP declared that he has received support from the Italian Haematology Society to attend and present a lecture on immunodeficiency in multiple myeloma. This interest was classified as personal pecuniary, non-specific meaning that GP can participate in discussions on all guideline topics, as expenses not beyond reasonable amounts.
- GP declared that he is the chief investigator (and designed trial protocol) for the PICCLE trial (parp inhibitor olaparib in relapsed chronic lymphocytic leukaemia). Astra Zeneca provided free drug support and the trial was supported by Leukaemia Lymphoma Research. This interest was classified as non-personal pecuniary, non-specific meaning that GP can participate in discussion of all guideline topics as chronic lymphocytic leukaemia is not being investigated by the guideline.
- GP declared the he is principle investigator for the PADIMAC trial (Phase II study of bortezomib, adramycin, dexamethasone therapy in previously untreated myeloma patients). Funded by Leukaemia Lymphoma Research. This interest was classified as non-personal pecuniary, (specific/non-specific TBC once clinical questions have been finalised), meaning that GP can participate in discussion of all guideline topics as he had no supervisory responsibility on the trial.
- GP declared that he is principle investigator for the GOYA study (GA-101 +CHOP versus RCHOP chemotherapy in untreated Diffuse Large B-cell NHL). Funded by Roche. This interest was classified as non-personal pecuniary, non-specific meaning

that GP can participate in discussion of all guideline topics as diffuse large B-cell NHL is not being investigated by the guideline.

- GP declared that he is principle investigator for the Lilly Myeloma trial (A Multicenter, Randomized, Double-Blind, Placebo-Controlled Phase 2/3 Study of Tabalumab in Combination with Bortezomib and Dexamethasone in relapsed by Myeloma). Funded by Lilly. This interest was classified as non-personal pecuniary, (specific/non-specific TBC once clinical questions have been finalised), meaning that GP can participate in discussion of all guideline topics as he had no supervisory responsibility on the trial.
- GP declared that he is principle investigator for the Gilead CLL study (A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of Idelalisib (GS-1101) in Combination with Bendamustine and Rituximab for Previously Treated Chronic Lymphocytic Leukemia). Funded by Gilead. This interest was classified as non-personal pecuniary, non-specific meaning that GP can participate in discussion of all guideline topics as lymphocytic chronic lymphocytic leukaemia is not being investigated by the guideline.
- GP declared that he is co-investigator (involved in designing the trial protocol) for the TEAMM trial (trial assessing the benefit of antibiotic prophylaxis with levofloxacin, and its effect on health care associated infections in patients with newly diagnosed symptomatic myeloma). Funded by NIHR Health Technology Assessment. This interest was classified as non-personal pecuniary, specific meaning that GP can participate in discussion of all guideline topics as the research is not funded by the healthcare industry.
- GP declared that he is co-investigator (involved in designing the trial protocol) for the BAP trial (bezafibrate/medroxyprogesteron in chronic lymphocytic leukaemia, acute myeloid leukaemia and non-Hodgkin's lymphoma). Funded by Queen Elizabeth Hospital Trust. This interest was classified as non-personal pecuniary, non-specific meaning that GP can participate in discussion of all guideline topics as chronic lymphocytic leukaemia, acute myeloid leukaemia and NHL are not being investigated by this guideline.
- GP declared that he is a member of the trial management group for a randomised phase II trial R2W in Waldenstron's macroglobulinaemia funded by Cancer Research UK. Involved in trial design, protocol amendments and answering clinical queries. This interest was classified as non-personal pecuniary, non-specific meaning that GP can participate in discussion of all guideline topics as Waldenstrons is not being investigated by the guideline.
- GP declared that he is a member of the data monitoring committee (checks safety data) for the LenaRIC trial (Phase II study of the adjuvant use of lenalidomide in patients undergoing reduced intensity conditioning allogenic transplantation for multiple myeloma). This interest was classified as non-personal pecuniary, (specific/non-specific TBC once clinical questions have been finalised), meaning that GP can participate in discussion of all guideline topics as he has no supervisory responsibility on the trial.
- GP declared that he is a member of the data monitoring committee(checks safety data) for HA-1 trial (A phase I clinical trial of the vaccination of healthy human volunteers against the minor histocompatibility antigen (mHAg) HA-1 using a DNA and MVA 'prime/boost' regimen). This interest was classified as non-personal pecuniary, non-specific meaning that GP can participate in discussion of all guideline topics as vaccination strategies are not being investigated by this guideline.
- GP declared that he is co-author on an evidence based position statement on bendamustine in multiple myeloma, on behalf of the UK Myeloma Forum and Myeloma UK published in 2013. This interest was classified as personal non-pecuniary, meaning that GP can participate in discussions of all guideline topics as conclusions of the paper were based on a review of the published evidence.

- GP declared that he is co-author on an evidence based position statement on maintenance and consolidation in multiple myeloma, on behalf of the UK Myeloma Forum and Myeloma UK published in March 2014. This interest was classified as personal non-pecuniary, meaning that GP can participate in discussion of all guideline topics as conclusions of the paper were based on a review of the published evidence and the guideline will not be investigating maintenance and consolidation therapy for myeloma.
- HS declared that he received reimbursement for travel expenses to attend the European Haematology Association annual meeting by Napp Pharmaceuticals. This interest was classified as personal pecuniary, non-specific meaning that HS can participate in discussion of all guideline topics as expenses not beyond reasonable amounts.
- HS declared that he is local principle investigator for the Myeloma X trial (Myeloma X (A phase III study to determine the role of a second autologous stem cell transplant as consolidation therapy in patients with relapsed multiple myeloma following prior high dose chemotherapy and autologous stem cell rescue). Funded by CRUK. This interest was classified as non-personal pecuniary, specific, meaning that HS can participate in discussions on all topics as no supervisory responsibility on the trial.
- HS declared that he is local principle investigator for the Myeloma XI trial (Randomised comparisons in myeloma patients of all ages of thalidomide, lenalidomide and bortezomib combinations and maintenance lenalidomide). Funded by CTAAC. This interest was categorised as non-personal pecuniary, (specific/non-specific TBC once clinical questions have been finalised), meaning that HS can participate in discussion of all guideline topics as he has no supervisory responsibility on the trial.
- HS declared that he is local principle investigator for the MM1 trial (investigating the effect of adding MLN9708 to the combination of lenalidomide and dexamethasone, improves survival in patients with relapsed myeloma). Funded by Millenium Pharmaceuticals. This interest was categorised as non-personal pecuniary, (specific/non-specific TBC once clinical questions have been finalised), meaning that HS can participate in discussion of all guideline topics as he has no supervisory responsibility on the trial.
- HS declared that he is local principle investigator for the PASS observational study (A non-interventional observational post authorisation safety study of subjects treated with lenalidomide). Funded by Celgene. This interest was categorised as non-personal pecuniary, (specific/non-specific TBC once clinical questions have been finalised) meaning that HS can participate in discussion of all guideline topics as he has no supervisory responsibility on the trial.
- HS declared that he is local principle investigator for the following trial: PREAMBLE observational study (non-interventional observational study aimed at understanding the real world effectiveness of novel agents used in treating multiple myeloma and their impact on patient-reported outcomes). Funded by Bristol Myers Squibb. This interest was classified as non-personal pecuniary, (specific/non-specific TBC once clinical questions have been finalised) meaning that HS can participate in discussion of all guideline topics as he has no supervisory responsibility on the trial.
- HS declared that he is a signatory on a myeloma endowment fund (generated by patient donations, no direct contributions from pharmaceutical industry). Used to fund small projects and provide additional resource for ongoing research projects. This interest was categorised as non-personal pecuniary, non-specific meaning that HS can participate in discussion of all guideline topics as no contributions from the fund are from the healthcare industry.
- JS declared that he has received an honorarium from MSD for chairing a meeting on antifungal drugs. This interest was classified as personal pecuniary, specific meaning

that JS must declare and withdraw from topics in which antifungal drugs are listed as an intervention until October 2014.

- JS declared that he has received an honorarium from Celgene for chairing a meeting on myeloma drugs. This interest was classified as personal pecuniary, specific meaning that JS must declare and withdraw from discussions on topics in which myeloma drugs manufactured by Celgene (thalidomide, lenalidomide and pomalidomide) as interventions until January 2015.
- JS received an honorarium from MSD for attending an advisory board on Posoconazole. This interest was classified as personal pecuniary, specific meaning that JS must declare and withdraw from discussions on topics which include posoconazle (antifungal) as an intervention until October 2014.
- JS declared that he has received reimbursement for accommodation, travel, subsistence and registration fee from MSD, to attend the American Society for Hematology conference in New Orleans. This interest was classified as personal pecuniary, non-specific meaning that JS can participate in discussion of all guideline topics as expenses were not beyond reasonable amounts.
- JS declared that he is co-applicant on a research grant from Pfizer to investigate characterisation of central brain processing of chemotherapy-induced peripheral neuropathy. This interest was classified as non-personal pecuniary, specific meaning that JS must declare and withdraw from discussion on topics which include pregablin (manufactured by Pfizer for treating peripheral neuropathy) as an intervention. However, as pharmacological management of neuropathic pain has been excluded from the topic on management of neuropathy JS can participate in discussions on all guideline topics.
- JS declared that he is the local principle investigator for the Myeloma XI trial (Randomised comparisons in myeloma patients of all ages of thalidomide, lenalidomide and bortezomib combinations and maintenance lenalidomide). Funded by CTAAC. This interest was classified as non-personal pecuniary, (specific/non-specific TBC once clinical questions have been finalised) meaning that JS can participate in discussions of all guideline topics as he has no supervisory responsibility on the trial.
- JS declared that he is local principle investigator for the RIC UCBT trial (Transplantation of umbilical cord blood from unrelated donors in patients with haematological diseases using a reduced intensity conditioning regimen). Funded by The Sue Harris Bone Marrow Trust. This interest was classified as non-personal pecuniary, non-specific meaning that JS can participate in discussions of all guideline topics as transplantation of umbilical cord blood is not being investigated by the guideline and he has no supervisory responsibility on the trial.
- JS declared that he is the local principle investigator for the MAC UCBT trial (Transplantation of umbilical cord blood from unrelated donors in patients with haematological diseases using a myeloablative conditioning regimen). Funded by The Sue Harris Bone Marrow Trust. This interest was classified as non-personal pecuniary, non-specific meaning that JS can participate in discussions of all guideline topics as umbilical cord blood is not being investigated by the guideline and he has no supervisory responsibility on the trial.
- JS declared that he is the local principle investigator for the LenaRIC trial (Phase II study of the adjuvant use of lenalidomide in patients undergoing reduced intensity conditioning allogenic transplantation for multiple myeloma). Funded by CTAAC. This interest was classified as non-personal pecuniary, (specific/non-specific TBC once clinical questions have been finalised) meaning that JS can participate in discussions of all guideline topics as he has no supervisory responsibility on the trial.
- JS declared that he is the local principle investigator for the ProT-4 trial (Phase II study to evaluate the efficacy of prophylactic transfer of CD4 lymphocytes after T-cell depleted reduced intensity HLA-identical sibling transplantation for

haematological cancers). Funded by Leukaemia and Lymphoma Research. This interest was classified as non-personal pecuniary, non-specific meaning that JS can participate in discussions of all guideline topics as transfer of lymphocytes after transplantation is not being investigated by the guideline and he has no supervisory responsibility on the trial.

- JS declared that he is the local principle investigator for the Myeloma IX trial (A randomised trial comparing second generation vs third generation bisphosphonates, induction chemotherapy regimens (CVAD vs CTD, and MP vs CTDa) and thalidomide maintenance vs no maintenance therapy). Funded by MRC. This interest was classified as non-personal pecuniary, (specific/non-specific TBC once clinical questions have been finalised) meaning that JS can participate in discussions of all guideline topics as he has no supervisory responsibility on the trial.
- JS declared that he is the local principle investigator for the Myeloma X relapse (intensive) trial (to determine whether a high-dose procedure with autologous transplant is superior to low-dose consolidation therapy following re-induction chemotherapy in patients with relapsed myeloma). Funded by CRUK. This interest was classified as non-personal pecuniary, specific meaning that JS can participate in discussions of all guideline topics as he has no supervisory responsibility on the trial.
- JS declared that he is the local principle investigator for the RICAZA trial (Phase II study of the tolerability of adjunctive azacitidine in patients undergoing reduced intensity allogeneic stem cell transplantation for acute myeloid leukaemia). Funded by Celgene. This interest was classified as non-personal pecuniary, non-specific meaning that JS can participate in discussions of all guideline topics as transplantation for acute myeloid leukaemia is not being investigated by the guideline and he has no supervisory responsibility on the trial.
- JS declared that he is the local principle investigator for the Living with advanced relapsed myeloma study (a cross sectional observational study to identify preventable and manageable late effects). Funded by Myeloma UK. This interest was classified as non-personal pecuniary, specific meaning that JS can participate in discussions of all guidelines topics as he has no supervisory responsibility on the trial.
- JS declared that he is the local principle investigator for the a Phase 2, Multi-centre, Randomised, Open-Label, Parallel Group Study to Evaluate the Effect of VELCADE on Myeloma related Bone Disease. Funded by Janssen-Cilag Ltd. This interest was classified as non-personal pecuniary, (specific/non-specific TBC once clinical questions have been finalised) meaning JS can participate in discussions of all guideline topics as he has no supervisory responsibility on the trial.
- JS declared that he is the local principle investigator for the UK Haplo Trial (A UK multicentre phase II study of haploidentical stem cell transplantation in patients with haematological Malignancies). Funded by Leukaemia Lymphoma Research. This interest was classified as non-personal pecuniary, non-specific meaning JS can participate in discussions on all guideline topics as he has no supervisory responsibility on the trial.
- JS declared that he is the local principle investigator for the HLA Epitope trial. (HLA-Epitope: Trial of HLA epitope matched platelet transfusion in aplastic anaemia, MDS and AML patients). Funded by NHS Blood and Transplant (NHSBT). This interest was classified as non-personal pecuniary, specific meaning that JS can participate in discussions on all guideline topics as aplastic anaemia, myelodisplastic syndrome and acute myeloid leukaemia are not being investigated by the guideline and he has no supervisory responsibility on the trial.
- JS declared that he is the principle investigator of a charitable grant from Royal Hallamshire Hospital Leukaemia and Research Fund, for a bolt-on study to Myeloma X, relating to supportive care in myeloma. This interest has been classified as non-personal pecuniary, specific (specific/non-specific TBC once clinical questions have

been finalised) meaning that JS can participate in discussions on all guideline topics as research is not funded by the healthcare industry.

- JS declared that he is co-investigator on the MUK5 trial (a phase II randomised trial of carfilzomib, cyclophosphamide and dexamethasone (CCD) vs cyclophosphamide, velcase and dexamethasone (CVD) for first relapse or primary refractory multiple myeloma). Funded by Myeloma UK. This interest has been classified as non-personal pecuniary, (specific/non-specific TBC once clinical questions have been finalised) meaning that JS can participate in discussions on all guideline topics as he has no supervisory responsibility on the trial.
- JS declared that he is co-investigator on the TEAMM trial (trial assessing the benefit of antibiotic prophylaxis and its effect on healthcare associated infections in patients with newly diagnosed symptomatic myeloma). Funded by NIHR Health Technology Assessment. This interest has been classified as non-personal pecuniary, specific meaning that JS can participate in discussions on all guideline topics as he has no supervisory responsibility on the trial.
- JS declared that he is co-investigator on the AML 17 trial (Working parties on leukaemia in adults and children trial in AML or high risk MDS 17). Funded by CRUK. This interest has been classified as non-personal pecuniary, non-specific meaning that JS can participate in discussions on all guideline topics as leukaemia, AML and MDS are not being investigated by the guideline and he has no supervisory responsibility on the trial.
- JS declared that he is co-investigator on the FiTT study (investigating the effectiveness of co-morbidity assessment in male patients with myeloma and prostate cancer). Funded by Weston Park Hospital Cancer Charity and Sheffield Teaching Hospitals NHS Foundation Trust. This interest has been classified as non-personal pecuniary, non-specific meaning that JS can participate in discussions on all guideline topics as he has no supervisory responsibility on the trial.
- JS declared that he is co-investigator on the AML 15 trial (Working parties on leukaemia in adults and children AML trial 15). Funded by MRC. This interest has been classified as non-personal pecuniary, non-specific meaning that JS can participate in discussions on all guideline topics as leukaemia is not being investigated by the guideline and he has no supervisory responsibility on the trial.
- JS declared that he is co-investigator on the AML 16 trial (A programme of development for older patients with AML and high risk MDS). Funded by CRUK. This interest was classified as non-personal pecuniary, specific meaning that JS can participate in discussions on all guideline topics as AML and MDS are not being investigated by the guideline and he has no supervisory responsibility on the trial.
- JS declared that he is co-investigator on the MCL MiniAllo trial (Phase II study of low intensity allogeneic transplantation in Mantle Cell Lymphoma). Funded by CRUK, Genzyme Therapeutics, National Institute for Health Research Cancer Network (NRCN). This interest was classified as non-personal pecuniary, non-specific meaning that JS can participate in discussions on all guideline topics as mantle cell lymphoma is not being investigated by the guideline and he has no supervisory responsibility on the trial.
- JS declared that he is co-investigator on the ORCHARRD trial (Ofatumumab rituximab chemoimmunotherapy ASCT relapsed refractory DLBCL). Funded by GlaxoSmithKline. This interest was classified as non-personal pecuniary, non-specific meaning that JS can participate in discussions on all guideline topics as diffuse large B-cell lymphoma is not being investigated by this guideline and he has no supervisory responsibility on the trial.
- JS declared that he is co-investigator on the FIGARO trial (A Randomised Trial of the FLAMSA-BU condItioning regimen in patients with AML and MDS undergoing allogeneic stem cell transplantation). Funded by Leukaemia and Lymphoma Research. This interest was classified as non-personal pecuniary, non-specific

meaning that JS can participate in discussions on all guideline topics as AML and MDS are not being investigated by the guideline and he has no supervisory responsibility on the trial.

- JS declared that he is co-investigator on the MUK 4 trial (A phase II trial of combination treatment with Vorinostat, bortezomib and dexamethasone in patients with relapsed multiple myeloma). Funded by Myeloma UK. This interest was classified as non-personal pecuniary, (specific/non-specific TBC once clinical questions have been finalised) meaning that JS can participate in discussions on all guideline topics as he has no supervisory responsibility on the trial.
- JS declared that he is co-investigator on the SarCaBon trial (A randomised phase II trial of Saracatinib versus placebo for cancer-induced bone pain). Funded by MRC. This interest was classified as non-personal pecuniary, non-specific meaning that JS can participate in discussions on all guideline topics as he has no supervisory responsibility on the trial.
- JS declared that he is a member of the UK Myeloma Forum. Involved in writing the evidence-based position statement: 'The use of consolidation and maintenance treatment in myeloma' which was published in March 2014. This interest was classified as personal non-pecuniary meaning that JS can participate in discussions on all guideline topics as the conclusions of the paper were based on a review of the published evidence and the guideline will not be investigating maintenance and consolidation therapy for myeloma.
- JS declared that he is a member of the UK Myeloma Forum and was involved in writing the evidence-based position statement: 'The use of bendamustine in myeloma'. This interest was classified as personal non-pecuniary meaning that JS can participate in discussions on all guideline topics as the conclusions of the paper were based on a review of the published evidence.
- JS declared that he is an executive member of the UK Myeloma forum, a non-profit organisation for the support of UK health professionals and scientists in the myeloma field. This interest was classified as personal non-pecuniary meaning that JS can participate in discussions on all guideline topics as this interest does not impact on the content of the guideline.
- JS declared that he is co-author of the following abstract which was prepared by BresMed on behalf of Celgene: 'Snowden J, Rodrigues F, Brereton N. 2012. Comparative Effectiveness of Lenalidomide plus Dexamethasone for the Treatment of Refractory/Relapsed Multiple Myeloma: A Systematic Review and Mixed Treatment Comparison. Blood (ASH Annual Meeting Abstracts); 120 (21): A4076'. This interest was classified as personal non-pecuniary meaning that JS must declare and withdraw from discussion of any topics which include drugs manufactured by Celgene (pomalidomide, lenalidomide, thalidomide) as interventions until November 2013.
- JS declared that he is co-author of the following abstract which was prepared by BresMed on behalf of Celgene: 'Stradwick S, Freemantle N, Vickers A, Rodrigues F, Monzini M, Brereton N, Snowden . 2013. Comparative Effectiveness of Lenalidomide Plus Dexamethasone Versus Bortezomib Subcutaneous for the Treatment of RRMM. Presented at the 14th International Myeloma Workshop (IMW); Kyoto, Japan; April 3–7'. This interest was classified as personal non-pecuniary meaning that JS must declare and withdraw from discussion of any topics which include drugs manufactured by Celgene (pomalidomide, thalidomide, lenalidomide) as interventions until April 2014.
- MJ declared that he has received an honorarium from Napp for attending an advisory board on bendamustine. This interest was declared as personal pecuniary, (specific/non-specific TBC once clinical questions have been finalised) meaning that MJ must declare and withdraw from discussion of any guideline topics which include bendamustine as an intervention until December 2014.

- MJ declared that he has received payment from Janssen for giving an interview on the delivery of bortazamib in the community setting. This interest was classified as personal pecuniary, (specific/non-specific TBC once clinical questions have been finalised) meaning that MJ must declare and withdraw from discussion of any guideline topics which include bortezomib as an intervention until December 2014.
- MJ declared that he has received payment from Celgene for chairing a debate on drug treatment of relapsed myeloma in Nov 2013. This interest was declared as personal pecuniary, specific meaning that MJ should withdraw from discussion of any guideline topics which include myeloma drugs manufactured by Celgene (thalidomide, lenalidomide, pomalidomide) as an intervention until November 2014.
- MJ declared that he has received reimbursement of travel and subsistence expenses from Napp to attend the American Society of Haematology meeting in New Orleans in Dec 2013. This interest was classified as personal pecuniary, non-specific meaning that MJ can participate in discussion of all guideline topics as expenses not beyond reasonable amounts
- MJ declared that he has received reimbursement of travel and subsistence expenses from Janssen to attend the International Myeloma Workshop in Japan in Dec 2013. This interest was classified as personal pecuniary, non-specific meaning that MJ can participate in discussion on all guideline topics as expenses not beyond reasonable amounts.
- MJ declared that he has received reimbursement for travel and subsistence expenses from Celgene to attend the European Haematology Association. This interest was declared as personal pecuniary, non-specific meaning that MJ can participate in discussions of all guideline topics as expenses not beyond reasonable amounts.
- MJ declared that he is local principle investigator for the MM1 trial (investigating the effect of adding MLN9708 to the combination of lenalidomide and dexamethasone, improves survival in patients with relapsed myeloma). Funded by Millenium Pharmaceuticals. This interest was classified as non-personal pecuniary, (specific/non-specific TBC once clinical questions have been finalised) meaning that MJ can participate in discussions of all guideline topics as he has no supervisory responsibility on the trial.
- MJ declared that he is local principle investigator for the FOCUS trial (Randomized, Open-label, Phase 3 Study of Carfilzomib vs Best Supportive Care in Subjects with Relapsed and Refractory Multiple Myeloma). Funded by Onyx Pharmaceuticals. This interest was classified as non-personal pecuniary, (specific/non-specific TBC once clinical questions have been finalised) meaning that MJ can participate in discussions of all guideline topics as he has no supervisory responsibility on the trial.
- MJ declared that he is local principle investigator for the MUK five trial (phase II randomised trial of carfilzomib, cyclophosphamide and dexamethasone (CCD) vs cyclophosphamide, velcade and dexamethasone (CVD) for first relapse or primary refractory multiple myeloma). Funded by Myeloma UK. This interest was classified as non-personal pecuniary, (specific/non-specific TBC once clinical questions have been finalised) meaning that MJ can participate in discussions on all guideline topics as he has no supervisory responsibility on the trial.
- MJ declared that he is the local principle investigator for the MUK four trial (Phase II Trial of combination treatment with Vorinostat, Bortezomib and Dexamethasone in participants with Relapsed Multiple Myeloma). Funded by Myeloma UK. This interest was classified as non-personal pecuniary, (specific/non-specific TBC once clinical questions have been finalised) meaning that MJ can take part in discussions on all guideline topics as he has no supervisory responsibility on the trial.
- MJ declared that he is the local principle investigator for the Myeloma IX trial (randomised trial comparing second generation vs third generation bisphosphonates, induction chemotherapy regimens (CVAD vs CTD, and MP vs CTDa) and

thalidomide maintenance vs no maintenance therapy). Funded by the Medical Research Council. This interest was classified as non-personal pecuniary, (specific/non-specific TBC once clinical questions have been finalised) meaning that MJ can participate in discussions on all guidelines topics as he has no supervisory responsibility on the trial.

- MJ declared that he is the local principle investigator for the Myeloma X trial (phase III on the role of a second autologous stem cell transplant in patients with relapsed myeloma following high dose rate chemotherapy and autologous stem cell rescue). Funded by Cancer Research UK. This interest was classified as non-personal, specific meaning that MJ can participate in discussions on all guideline topics as he has no supervisory responsibility on the trial.
- MJ declared that he is the local principle investigator for the Myeloma XI trial (Randomised comparisons in myeloma patients of all ages of thalidomide, lenalidomide and bortezomib combinations and maintenance lenalidomide). Funded by CTAAC. This interest was classified as non-personal pecuniary, (specific/non-specific TBC once clinical questions have been finalised) meaning that MJ can participate in discussions on all guideline topics as he has no supervisory responsibility on the trial.
- MJ declared that he is the signatory for a charitable hospital fund used for education and development for healthcare professionals. No contribution to this fund from the pharmaceutical industry. This interest was classified as non-personal pecuniary, non-specific meaning that MJ can participate in discussions on all guideline topics as there are no contributions to the fund from the healthcare industry.
- MJ declared he was part of the group who developed evidence based guidelines on myeloma for the BCSH. This interest was classified as personal non-pecuniary meaning that MJ can participate in discussions on all guideline topics as the interest does not impact on the content of the guideline.
- MS declared that he has received payment from Celgene for attending and advisory board on lenalidomide usage in myeloma. This interest was declared as personal pecuniary, (specific/non-specific TBC once clinical questions have been finalised) meaning that MS must declare and withdraw from discussion on any guideline topics which include lelalidomide as an intervention until June 2014.
- MS declared that he has received reimbursement for travel and subsistence expenses from Janssen, for attending the International Myeloma Workshop. This interest was classified as personal pecuniary, non-specific meaning that MS can participate in discussions on all guideline topics as expenses not beyond reasonable amounts.
- MS declared that he has received payment from Celgene for giving presentations on: “Optimising Myeloma therapy" in November 2013. This interest was classified as personal pecuniary, specific meaning that MS must declare and withdraw from discussions on all guideline topics which include myeloma drugs manufactured by Celgene (thalidomide, lenalidomide and pomalidomide) as an intervention until November 2014.
- MS declared that he has received payment from Celgene for giving a presentation on: "Pomalidomide Case Histories" in November 2013. This interest was classified as personal pecuniary, (specific/non-specific TBC once clinical questions have been finalised) meaning that MS must declare and withdraw from discussions on any guideline topics which include pomalidomide as an intervention until November 2014.
- MS declared that he has received payment from Janssen for giving a presentation on: "Transplant: what is the data telling us?" Provided data on induction chemotherapy prior to transplant in October 2013. This interest was classified as personal pecuniary, specific meaning that MS must declare and withdraw from discussion of any guideline topics which include induction chemotherapy as an intervention until October 2014. Induction chemotherapy is not being investigated by

the guideline as there is a NICE Technology Appraisal in development in this area, therefore MS will be able to participate in discussion of all guideline topics.

- MS declared that he has received payment from Celgene for giving a presentation on: "Pomalidomide Background: Summary of Recent Data" in September 2013. This interest was classified as personal pecuniary, (specific/non-specific TBC once clinical questions have been finalised) meaning that MS must declare and withdraw from discussion of any guideline topics which include pomalidomide as an intervention until September 2014.
- MS declared that he has received payment from Janssen for giving a presentation on: "Managing Patient's Expectations" in May 2013. This interest was classified as personal pecuniary, non-specific meaning that MS can participate in discussions on all guideline topics as the subject of the presentation is not specific to the content of the guideline.
- MS declared that he has received payment from Celgene for giving a presentation on: "Myeloma treatment in South East London" in February 2013. This interest has been classified as personal pecuniary, specific meaning that MS must declare and withdraw from discussion on all guideline topics which include myeloma drugs manufactured by Celgene (thalidomide, lenalidomide and pomalidomide) as an intervention until February 2014.
- MS has declared that he had a consultative role on the Burden of Relapse study (a non-treatment related clinical study examining the impact (physical, psychological, economic) of periods of remission in comparison to periods of disease activity). He received payment from Celgene for teleconference participation every few months and review of data. The last teleconference was in Jan 2014 and he has withdrawn for the duration of the guideline. This interest was classified as personal pecuniary, specific meaning that MS must declare and withdraw from discussions of all guideline topics which include myeloma drugs manufactured by Celgene (thalidomide, lenalidomide and pomalidomide) as an intervention until January 2015.
- MS declared that he is the chief investigator of the MM013 study (Phase 2 multicentre, open-label study to determine the efficacy and safety of pomalidomide in combination with low dose dexamethasone in subjects with relapsed or refractory myeloma). The trial is funded by Celgene. MS was not involved in designing the trial protocol. This interest was classified as non-personal pecuniary, (specific/non-specific TBC once clinical questions have been finalised) meaning that MS must declare and withdraw from discussion of all guideline topics which include pomalidomide as an intervention.
- MS declared that he is the local principle investigator for the PADIMAC study (Phase II study of Bortezomib, Adriamycin and Dexamethasone (**PAD**) therapy for previously untreated patients with multiple myeloma: **I**mpact of minimal residual disease (**M**RD) in patients with deferred **A**S**C**T). Funded by Leukaemia & Lymphoma Research. This interest was classified as non-personal pecuniary, (specific/non-specific TBC once clinical questions have been finalised) meaning that MS can participate in discussions on all guideline topics as he has no supervisory responsibility on the trial.
- MS declared that he is local principle investigator for the TEAMM trial (trial assessing the benefit of antibiotic prophylaxis with levofloxacin, and its effect on health care associated infections in patients with newly diagnosed symptomatic myeloma). Funded by the NIHR Health Technology Assessment. This interest was classified as non-personal pecuniary, specific meaning that MS can participate in discussions on all guideline topics as he has no supervisory responsibility on the trial.
- MS declared that he is local principle investigator for the CLARION trial (Randomized, Open-label Phase 3 Study of Carfilzomib, Melphalan, and Prednisone versus Bortezomib, Melphalan, and Prednisone in Transplant ineligible Patients with Newly Diagnosed Multiple Myeloma). Funded by Onyx Therapeutics. This interest was declared as non-personal pecuniary, (specific/non-specific TBC once clinical

questions have been finalised) meaning that MS can participate in discussions on all guideline topics as he has no supervisory responsibility on the trial.

- MS declared that he is local principle investigator for the CNTO328 trial (Siltuximab (compared with placebo) in Patients With High-risk Smoldering Multiple Myeloma). Funded by Janssen. This interest was declared as non-personal pecuniary, (specific/non-specific TBC once clinical questions have been finalised) meaning that MS can participate in discussions of all guideline topics as he has no supervisory responsibility on the trial.
- MS declared that he is local principle investigator for the PASS observational study (A non-interventional observational post authorisation safety study of subjects treated with lenalidomide). Funded by Celgene. This interest was classified as non-personal pecuniary, (specific/non-specific TBC once clinical questions have been finalised) meaning that MS can participate in discussions on all guideline topics as he has no supervisory responsibility on the trial.
- MS declared that he is principle investigator for a phase III trial in relapsed myeloma (patients randomised between daratumumab with lenalidomide and dexamethasone versus lenalidomide and dexamethasone alone). Funded by Janssen. This interest has been classified as non-personal pecuniary, (specific/non-specific TBC once clinical questions have been finalised) meaning that MS can participate in discussions on all guideline topics as he has no supervisory responsibility on the trial.
- MS declared that he has written a position statement for the UK Myeloma Forum, about horizon scanning for new agents in myeloma. Statement does not advocate any particular agents. This interest has been classified as personal non-pecuniary meaning that MS can participate in discussions on all guideline topics as this interest does not impact on the content of the guideline.
- MS declared that he is planning to write a review of the long-term follow up data for a trial on pomalidomide. This interest has been classified as personal non-pecuniary. MS to inform GDG when review is published.
- SA declared that an honorarium from MSD was paid to his department for giving a lecture on: 'The Science of Symptoms'. This interest was classified as non-personal pecuniary, non-specific meaning that HA can participate in discussions of all guideline topics as the subject of the presentation is not specific to the content of the guideline.
- SA declared that an honorarium from Creative Ceutical was paid to his department for taking part in a teleconference to set up an interview study of quality of life in advanced breast cancer. This interest was classified as non-personal pecuniary, non-specific meaning that SA can participate in discussions on all guideline topics as advanced breast cancer is not being investigated by the guideline.
- SA declared that an honorarium from Amgen was paid to his department for giving a lecture on metastatic bone disease. This interest was classified as non-personal pecuniary, non-specific meaning that SA can participate in discussions on all guideline topics as metastatic bone disease is not being investigated by the guideline
- SA declared that an honorarium from Napp Pharmaceuticals was paid to his department for taking part in an advisory board on pain. This interest was classified as non-personal pecuniary, non-specific meaning that SA can participate in discussions on all guideline topics as management of pain is not being covered by the guideline.
- SA declared that an honorarium from Prostrakan was paid to his department for giving a lecture on introduction to nausea and vomiting and its management. This interest was classified as non-personal pecuniary, non-specific meaning that SA can participate in discussions on all guideline topics as management of nausea and vomiting is not being investigated by the guideline.
- SA declared that an honorarium from Archimedes was paid to his department for participating in the Archimedes Academy. This interest was classified as non-

personal pecuniary, non-specific meaning that SA can participate in discussions on all guideline topics as the payment was not beyond reasonable expenses.

- SA declared that an honorarium from the World Association for Sleep Management was paid to his department for participating in their symposium. This interest was classified as non-personal pecuniary, non-specific meaning that SA can participate in discussions on all guideline topics as the subject of the presentation is not specific to the content of the guideline.
- SA declared that an honorarium from Gruenthal was paid to his department for participating in an advisory board on education and awareness strategies for breakthrough cancer pain. This interest was classified as non-personal pecuniary, non-specific meaning that SA can participate in discussions on all guideline topics breakthrough cancer pain is not being investigated by the guideline.
- SA declared that an honorarium from Bayer was paid for taking part in a meeting on Sativex. This interest was classified as non-personal pecuniary, specific meaning that SA can participate in discussions on all guideline topics as pharmacological management of neuropathic pain has been excluded from the topic on management of neuropathy.
- SA declared that he is chief investigator for a study to investigate characterisation of central brain processing of chemotherapy-induced peripheral neuropathy. Funded by Pfizer. This interest was classified as non-personal pecuniary, specific meaning that SA must declare and withdraw from discussions on guideline topics which include pregablin as an intervention (manufactured by Pfizer for treating peripheral neuropathy). As pharmacological management of neurpathic pain had been excluded from the topic on management of neutopathy SA can participate in all discussions on this topic.
- SA declared that he is chief investigator for an observational study looking at a new treatment for opioid-induced constipation in cancer patients. Study is funded by Astra Zeneca. This interest was classified as non-personal pecuniary, non-specific meaning that SA can participate in discussions on all guidelines topics as management of opiod induced constipation is not being investigated by the guideline.
- SA declared that he is chief investigator for the a study of an experimental new opioid for pain control in cancer patients. Study is funded by Grunenthal. This interest was classified as non-personal pecuniary, non-specific meaning that SA can participate in discussions on all guidelines topics as pain control is not being investigated by the guideline.
- SA declared that he is chief investigator for a study on a pain killer for cancer and non-cancer patients. Study is funded by Mundi Pharma. This interest was classified as non-personal pecuniary, non-specific meaning that SA can participate in discussions on all guidelines topics as pain control is not being investigated by the guideline.
- SA declared that he is chief investigator for a study to measure the response to ‘Standard laxative treatment’ (SLT) in patients with opioid-induced constipation, across several European countries. Study is funded by Mundi Pharma. This interest was classified as non-personal pecuniary, non-specific meaning that SA can participate in discussions on all guidelines topics as management of opiod induced constipation is not being investigated by the guideline.
- SA declared that he is chief investigator for the a study to investigate HRQOL of triple negative breast cancer patients. Funded by Creative Ceutical This interest was classified as non-personal pecuniary, non-specific meaning that SA can participate in discussions on all guidelines topics as breast cancer is not being investigated by the guideline.
- SA declared that he is co-investigator of a trial of an experimental drug to treat bone cancer pain in cancer patients. Trial is funded by the MRC and Astra Zeneca. This interest was classified as non-personal pecuniary, non-specific meaning that SA can

participate in discussions on all guidelines topics as pain control is not being investigated by the guideline and he has no supervisory responsibility on the trial.

- SA declared that he is a fund holder for the SPORG research group. Money is spent on supportive and palliative care research. No contributions to the fund from pharmaceutical companies. This interest was classified as non-personal pecuniary, non-specific meaning that SA can participate in discussions on all guidelines topics as there are no contributions to the fund from the healthcare industry.
- NM declared that she is principle investigator for a trial on biomarkers in lymphoma. Involved in designing the trial protocol. Trial has not yet started as no funding agreed – there will not be any commercial funding. This interest was classified as non-personal pecuniary, non-specific. NM to inform when the trial is funded and what the funding source is
- NM declared that she is the sub-investigator for the ZEST study (Zevalin for older people with diffuse large B cell lymphoma). Funded by Spectrum Pharmaceuticals. Involvement is to administer the drug – not involved in collecting or analysing data. This interest was classified as non-personal pecuniary, non-specific meaning that NM can participate in discussions on all guideline topics as diffuse large B cell lymphoma is not being investigated by the guideline and she has no supervisory responsibility on the trial.
- AG declared that she has attended a symposium on Pomalidomide organised by Celgene. No fee was received. The symposium was to present data on this drug. This interest was classified has personal non-pecuniary meaning that AG can participate in discussions on all guideline topics as no fee was received.
- MM declared that she has received an honorarium for attending a nurse educational event held by Janssen on the supportive care needs of patients with myeloma in May 2013. This interest was classified as personal pecuniary, specific meaning that MM must declare and withdraw discussion of all guideline topics which include the supportive needs of patients until May 2014.

The following new interests were declared at the meeting:

- CM declared that he had received reimbursement of travel expenses from the organisers for speaking on myeloma to data managers at the European Blood and Marrow Transplant meeting in March 2014. This interest was categorised as personal pecuniary non-specific meaning that CM can declare and participate in discussion of all topics as the expenses were not beyond reasonable amounts.
- JS declared that he had received reimbursement of travel expenses from the organisers for speaking on quality in transplantation at the Joint Accreditation Committee in Autoimmune Diseases meeting in March 2014. This interest was categorised as personal pecuniary non-specific meaning that CM can declare and participate in discussion of all topics as the expenses were not beyond reasonable amounts.

The GDG were reminded that if they take on any new interests, these must be declared to the NCC-C as soon as they happen so that the necessary action can be taken.

3. Discussions

The GDG were given presentations on:

- Introduction to NICE
- Introduction to NCC-C
- Timetable for guideline development and housekeeping
- Patient/Carer involvement in guideline development
- Guideline methodology development: From evidence to recommendations

- Guideline methodology development: Health Economics in NICE guidelines
- Technology appraisals and clinical guidelines.

The GDG discussed the guideline scope and the topics that will be investigated. The group then drafted and agreed a PICO question for topics A, B, C1-2, D1-2, E, F, G, H, K, L1-3, M, N, O & Q

The GDG discussed topics which were potential priorities for economic investigation.

4. Close of meeting

CM thanked the GDG for their input to the meeting, reminded them that the next meeting would be on **Thursday 1st May 2014,** starting at 10.30 in the Board Room, NCC-C, Cardiff and closed the meeting.