MINUTES
CIBMTR WORKING COMMITTEE FOR HODGKIN & NON-HODGKIN LYMPHOMA
Orlando, Florida
Thursday, February 25, 2010, 2:45 pm - 4:45 pm

Co-Chair: Hillard M. Lazarus, MD, Case Western Reserve University Ireland Cancer Center, Cleveland, OH
Telephone: 216-844-3629; Fax: 216-844-5979; E-mail: hml@po.cwru.edu

Co-Chair: Ginna Laport, MD, Stanford University Medical Center, Stanford, CA
Telephone: 650-723-0822; Fax: 650-725-8950; E-mail: glaport@stanford.edu

Co-Chair: Silvia Montoto, St. Bartholomew’s Hospital 45 Little Britain; Telephone: 44 207-601-7456; Fax: 44-207-796-3979;
E-mail: s.montoto@qmul.ac.uk

Statisticians: Jeanette Carreras, MPH, CIBMTR Statistical Center
Telephone: 414-805-0681; Fax: 414-805-0714; E-mail: j carrera@mcw.edu
Mei-Jie Zhang, PhD, CIBMTR Statistical Center
Telephone: 414-456-8375; Fax: 414-805-0714; E-mail: meijie@mcw.edu

Scientific Director: Parameswaran Hari, MD, MS, Medical College of Wisconsin, Milwaukee, WI
Telephone: 414-805-4613; Fax: 414-805-0714; E-mail: phari@mcw.edu

1. Introduction
The CIBMTR Working Committee for Hodgkin & Non-Hodgkin Lymphoma met on Thursday February 25, 2010 at 2:45 pm. Dr Hillard Lazarus welcomed everyone and explained the attendance sheet, evaluation and voting system to the audience. All the members of the Committee were encouraged to find more information regarding CIBMTR proposals submission process at www.cibmtr.org. Dr Lazarus welcomed and introduced Dr David Maloney as the newly appointed Chair for the Hodgkin & Non-Hodgkin Lymphoma Working Committee. Dr Hillard Lazarus was acknowledged for all of his efforts during these past 19 years. The minutes of the February 2009 meeting were approved.

2. Accrual summary
Because of a full agenda, the accrual summary was not discussed in further detail, but included as part of the CIBMTR Working Committee attachments at www.cibmtr.org. Any member of the Committee interested in proposing a study can look at the accrual summary.

As accustomed a significant increase in activity of the Working Committee was reported last year including 4 published papers, 4 manuscripts in preparation, 3 presentations at the American Society of Hematology in New Orleans, 1 oral presentation at the BMT Tandem Meetings in Orlando, FL and 1 presentation at the T-cell Lymphoma Forum in Maui, Hawaii. An acknowledgment was given for the outstanding achievement of the Lymphoma Working Committee.

3. Presentations and published papers
Dr Lazarus informed the audience that the Committee has four (4) published manuscripts in BBMT (D98-10, LY03-01, LY04-02 and LY05-03), three (3) presentations at the American Society of Hematology in New Orleans (LY04-01, LY06-03 and LY06-06), one (1)
presentation at the BMT Tandem Meetings in Orlando (LY04-03) and one (1) presentation at
the T-cell Lymphoma Forum in Maui, Hawaii (LY06-05).

a. Publications:
   D98-10 Koen van Besien, Jeanette Carreras, Philip J. Bierman, Brent R. Logan, Arturo Molina,
   M. Vose, Parameswaran N. Hari. Unrelated donor hematopoietic cell transplantation for non-

b. LY03-01 Fenske TS, Hari PN, Carreras J, Zhang MJ, Kamble RT, Bolwell BJ, Cairo MS,
   Champlin RE, Chen YB, Freytes CO, Gale RP, Hale GA, Ilhan O, Khoury HJ, Lister J,
   Maharaj D, Marks DI, Munker R, Pecora AL, Rowlings PH, Shea TC, Stiff P, Wiernik PH,
   Winter JN, Rizzo JJD, Van Besien K, Lazarus HM, Vose JM. Impact of pre-transplant
   rituximab on survival after autologous hematopoietic stem cell transplantation for diffuse large

c. LY04-02 Lazarus HM, Zhang MJ, Carreras J, Hayes-Lattin BM, Aetaergin AS, Bitran JD,
   Bolwell BJ, Freytes CO, Gale RP, Goldstein SC, Hale GA, Inwards DJ, Klumpp TR, Marks DI,
   Maziarz RT, McCarthy PL, Pavlovsky S, Rizzo JD, Shea TC, Shouten HC, Slavin S, Winter
   JN, Van Besien K, Vose JM, Hari PN. A comparison of HLA-identical sibling allogeneic
   versus autologous transplantation for diffuse large B-cell lymphoma: a report from the

d. LY05-03 Devetten MP, Hari P, Carreras J, Logan BR, van Besien K, Bredeson CN, Freytes
   CO, Gale RP, Gibson J, Giralt SA, Goldstein SC, Gupta V, Marks DI, Maziarz, Vose JM,
   Lazarus HM, Anderlini P. Unrelated donor reduced-intensity and nonmyeloablative stem cell

e. Presentations:
   LY04-01 Gregory Hale, Smriti Shrestha, Jennifer Le-Rademacher, Hillard M. Lazarus, Ginna
   Laport, Silvia Montoto and Parameswaran Hari. Alternative donor hematopoietic cell
   transplantation after reduced intensity or nonmyeloablative conditioning in advanced non-
   Hodgkin lymphoma. *Presentation at the American Society of Hematology in New Orleans,
   LA, December 2009.*

f. LY06-03 Anna Sureda, Mei-Jie Zhang, Parameswaran Hari, Silvia Montoto, Ginna Laport,
   Hillard Lazarus, Michel Attal, Nigel H Russel, Kirsty Thomson, Jean-Paul Vernant, Carme
   Canals, Harold Schouten, Marcelo C. Pasquini. Comparison of unrelated and sibling donor
   allogeneic hematopoietic cell transplantation for follicular lymphoma. *Presentation at the
   American Society of Hematology in New Orleans, LA, December 2009.*

g. LY06-06 Theresa Hahn, Philip L McCarthy, Jeanette Carreras, Mei-Jie Zhang, Hillard M.
   Lazarus, Ginna Laport, Silvia Montoto and Parameswaran Hari. Comparison of prognostic
   models for autologous hematopoietic stem cell transplantation for relapsed Hodgkin lymphoma.
   *Oral presentation at the American Society of Hematology in New Orleans, LA, December
   2009.*

h. LY04-03 Richard T. Maziarz, Zhiwei Wang, Mie-Zhang, Ginna Laport, Hillard Lazarus, Silvia
   Montoto, Parameswaran Hari. CNS remission predicts survival after autologous hematopoietic
   stem cell transplantation for non-Hodgkin's lymphoma with pre-existing CNS involvement: a
   CIBMTR analysis. *Oral Presentation at the BMT Tandem Meetings in Orlando, FL,*
February 2010.

4. Studies in progress
   a. **LY04-01:** Alternative donor hematopoietic cell transplantation after reduced intensity or nonmyeloablative conditioning in advanced non-Hodgkin lymphoma (G Hale): Current status: manuscript preparation. This study was presented at the American Society of Hematology in New Orleans. The study analyzed the outcomes of 248 (61% male) adult recipients of HCT for NHL from alternative donors after RIC/NMA conditioning reported to the CIBMTR from 1997 to 2004. Recipients of any prior transplants and those in first complete remission from follicular NHL were excluded. Outcomes of TRM, progression, progression-free survival and overall survival were analyzed in multivariate regression models adjusting for key pre-transplant variables. In NHL patients without sibling donor options, alternative donor HCT with RIC/NMA conditioning results in favorable long-term survival although advanced age, histology and resistant disease status remain concerning. Higher grade NHL, use of ATG or T-cell depletion and HLA mismatch were associated with inferior outcomes. Lack of an available sibling donor should not be a barrier to allogeneic HCT in the appropriate patient.

   b. **LY04-03:** CNS remission predicts survival after autologous hematopoietic stem cell transplantation for non-Hodgkin's lymphoma with pre-existing CNS involvement (R Maziarz). Current status: analysis. This study was an oral presentation at the BMT Tandem Meetings in Orlando. Dr Richard Maziarz presented the study along with LY09-04 (comparison study). The study analyzed the outcomes of 151 (64% male) adult recipients of AHCT with NHL and CNS involvement identified at any time prior to transplant and compared them to 4688 AHCT with no CNS lymphoma involvement during the years 1990-2005. Median follow-up of survivors was 77 months. No statistically significant differences in outcomes non-relapse mortality, relapse, DFS or OS were identified between the two groups. Patients with CNS remission (96/151) at time of AHCT had significantly superior survival compared with those with active CNS disease (55/151) at transplant. Significantly higher relapse rates with an associated diminished DFS and OS (3 year OS 14%) were found in patients with active disease. Excellent long-term survival is possible after AHCT in NHL patients with prior CNS involvement despite adverse baseline prognostic factors. However, best outcomes are in patients who achieve a CNS remission prior to transplant.

   c. **LY05-01:** Effectiveness of donor leukocyte infusion in the management of relapsed lymphoma after allogeneic stem cell transplant (M Tomblyn): Current status: data collection. Dr Marcie Tomblyn presented the study. This study would like to evaluate outcomes after donor leukocyte infusion for patients who have relapsed or progressed after allogeneic matched related or unrelated donor stem cell transplant for management of lymphoma. The study population will includes 152 patients with non-Hodgkin or Hodgkin’s lymphoma that were treated with a matched related or unrelated donor transplant, relapsed and subsequently received a DLI between 1995-2008. Comments from the Writing Committee members to be considered at the data file preparation phase were presented and discussed. The Committee was informed the response rate of 1/3 if a supplemental form is requested. The Committee suggested targeting center Directors with the majority of DLI cases to see if they are keen to fill-in the supplemental form.

   d. **LY06-02:** Nonmyeloablative allogeneic hematopoietic stem cell transplantation in patients who experience relapse after autologous stem cell transplantation for lymphoma (C Freytes): Current status: manuscript preparation.

   e. **LY06-03:** Comparison of unrelated and sibling donor allogeneic hematopoietic cell transplantation for follicular lymphoma (A Sureda): Current status: manuscript preparation. This study was presented at the American Society of Hematology in New Orleans. Dr Marcelo Pasquini presented on behalf of Dr Anna Sureda. This study compared the outcomes of 702 recipients of allogeneic HCT for FL (198 unrelated and 504 sibling donors) from 171 centers
world-wide reporting to the CIBMTR or EBMT between 1997 and 2005. This study shows that unrelated HCTs are performed later in the treatment course for FL, in higher risk patients, most commonly with reduced intensity conditioning, and are associated with worse PFS and OS compared to sib HCT. The authors are writing up the manuscript and addressing the Writing Committee comments. Plan to present this study at the upcoming EBMT meeting.

f. **LY06-05:** Comparison of autologous vs allogeneic stem cell transplantation for T-cell NHL (S Smith): Current status: analysis. This study was presented at the T-cell Lymphoma Forum in Maui, Hawaii. Dr Sonali Smith presented the study. The main objective was to compare outcomes of autologous versus allogeneic hematopoietic stem cell transplantation in a large group of patients with T-NHL regarding non-relapse mortality, disease progression, PFS, and OS. The population was restricted to 113 autologous, 66 HLA-identical sibling and 40 unrelated patients ≤ 60 years old with mature T-NHL transplanted between 1996-2005, and with at least one year of follow up. The preliminary analysis suggests that there is no difference in outcome between autologous versus allogeneic stem cell transplant for patients with relapsed T-NHL in terms of PFS and OS. Non-relapse mortality was higher in patients undergoing allogeneic stem cell transplant. For patients undergoing allogeneic stem cell transplant, there was no difference in outcome between matched related and matched unrelated donor transplants, and there was no difference in outcome between myeloablative and non-myeloablative stem cell transplant. Plan to submit an ASH abstract this year.

g. **LY06-06:** Comparison of prognostic models for autologous hematopoietic stem cell transplantation for relapsed Hodgkin lymphoma (P McCarthy): Current status: analysis. This study was presented at the American Society of Hematology in New Orleans. Dr Theresa Hahn presented the study. The study compared 3 models from Dana-Farber Cancer Institute (DFCI), Roswell Park Cancer Institute (RPCI) and University of Minnesota (UMinn) in an independent multicenter dataset of 597 relapsed or refractory HL patients receiving AHCT from 1996-2004, reported to the CIBMTR by 150 centers. The DFCI model risk factors were: chemo-resistant disease, KPS<90, ≥1 extranodal site; with corresponding risk groups low (0 factors), intermediate, (1 factor) and high (2-3 factors). The RPCI model risk factors were: chemo-resistant disease, KPS<90, ≥3 prior regimens with risk groups low (0-1 factor) and high (2-3 factors). The UMinn model risk factors were: chemo-resistant disease, B symptoms, not in CR at BMT with risk groups low (0-1 factor), intermediate (2 factors) and high (3 factors). Only 1 factor (chemo- resistant disease) was included in all 3 models. The high risk group PFS was similar for the DFCI and RPCI models but the DFCI model separated a low and intermediate risk group which were not significantly different from each other. The UMinn model high risk group had a higher PFS than either of the other 2 models’ high risk group and the intermediate group in this model was not significantly different from the high risk group. The relative incremental change in $R^2$ was 26% higher for the DFCI than the RPCI model and 120% higher for the RPCI than the UMinn model. From the B and $R^2$ values, the DFCI model had marginal superiority over RPCI model while both performed better than the UMinn model. Plan to validate the study with 187 additional cases from the CIBMTR.

h. **LY07-02:** Transplant outcomes in the mycosis fungoides and sezary syndrome patients (M Lechowicz): Current status: analysis. Dr Mary Jo Lechowicz presented the study. Forty nine cases transplanted from 1999-2007 were identified in the CIBMTR and had full report forms. Only 48 patients, each with at least 2 years of follow-up, were used for analysis. The primary outcomes described in the study were treatment-related mortality, overall survival and progression-free survival, progression relapse, hematopoietic recovery (neutrophil and platelet engraftment), AGVHD II-IV and cGVHD. The median follow-up of survivors was 37 (3-102) months. Working Committee suggestions: include 5-year survival and type of disease progression at 6 months. Plan to submit an ASH abstract this year.
i. **LY08-01**: Outcomes of allogeneic and autologous hematopoietic progenitor cell transplant for Burkitt’s and Burkitt-like lymphoma (J Gajewski): Current status: data file preparation. Dr James Gajewski presented the study. There are 72 autologous, 54 HLA identical sibling and 39 unrelated/mismatched related patients who underwent transplantation for Burkitt’s lymphoma reported to the CIBMTR from 1985 and 2006. Per the study Writing Committee cord blood and CR1 patients will be added to the analysis (CR1 will be analyzed separately). Plan to submit an ASH abstract this year.

j. **LY08-02**: Outcome of patients with mantle cell lymphoma treated with autologous versus allogeneic transplantation (T Fenske): Current status: data file preparation. Dr Timothy Fenske presented the study. This study compares the clinical outcomes between 401 autologous, 101 myeloablative and 191 RIC/NST patients reported to the CIBMTR from 1996-2006 undergoing stem cell transplantation for mantle cell non-Hodgkin lymphoma as to the following: 100-day mortality, engraftment (neutrophil recovery; platelet transfusion), acute and chronic graft-versus-host disease, treatment related mortality, disease recurrence or progression, progression-free survival and overall survival. Plan to submit an abstract to the 11th International Conference on Malignant Lymphoma in Lugano.

k. **LY08-03**: Comparison of reduced and standard conditioning in allogeneic stem cell transplantation in patients with B-cell non Hodgkin’s lymphoma (U Bacher): Current status: data file preparation. Dr Ulrike Bacher presented the study. This study intends to compare clinical outcomes and complications of reduced intensity or non-myeloablative (n=94) vs myeloablative conditioning regimens (n=103) in allogeneic stem cell transplantation in patients aged ≥18 with diffuse large B-cell lymphoma reported to the CIBMTR from 1997-2006. Question regarding excluding HLA identical sibling from the study was raised to the Committee. There are no prior autologous transplants in this study.

l. **LY09-01**: Clinical outcomes of hematopoietic stem cell transplantation in patients with diffuse large B cell lymphoma transformed from chronic lymphocytic leukemia, follicular lymphoma or waldenstrom macroglobulinemia (B Wirk): Current status: protocol development. Dr Wirk presented the study. There are 173 autologous, 41 myeloablative and 40 NST/RIC patients who underwent hematopoietic stem cell transplantation in patients with diffuse large B cell lymphoma transformed from chronic lymphocytic leukemia and follicular lymphoma reported to the CIBMTR, from 1990-2005. Dr Timothy Fenske new proposal PROP 1209-20: “Outcome of patients with transformed non-Hodgkin lymphoma treated with autologous versus allogeneic transplantation” overlaps with this approved study. There was a consensus of merging these two studies and include Dr Linda Burns as co-principal investigator since she proposed a similar idea years ago.

m. **LY09-02**: Comparison of non myeloablative allogeneic stem cell transplantation as upfront salvage therapy for relapsed lymphoma compared to a strategy of utilizing nonmyeloablative allogeneic stem cell transplantation after autologous transplant failure (C Freytes): Current status: protocol development. Dr Freytes presented the study. The specific aim is to compare the clinical outcome of patients with lymphoma who undergo nonmyeloablative allogeneic stem cell transplantation (NST) as upfront salvage therapy for relapsed lymphoma to the outcome of patients who received NST after autologous stem cell transplant failure. A total of 91 patients with upfront NST/RIC conditioning regimen, 402 patients with upfront autologous and 150 patients with salvage NST/RIC after autologous transplant were presented. The main problem with the outcome analysis is to determine the timing of when the clock starts for all the patients. We need to put everybody on the same timing. Might need probabilities for each group. Plan to do the same analysis as one of the MDS approved studies. After voting, the Committee decided to defer the study for an additional fiscal year.

n. **LY09-03**: A retrospective review of involved field radiotherapy pre or post-high dose chemotherapy and autologous stem-cell transplant in refractory or relapsed patients with
Hodgkin’s lymphoma (H Miller): Current status: protocol development. Dr Silvia Montoto presented on behalf of Dr Miller. The role of involved field radiation therapy pre or post high dose chemotherapy with autologous stem cell rescue for patients who have refractory or relapsed Hodgkin’s Lymphoma has not been clearly defined. This retrospective review aims to analyze refractory and relapsed HL patients who have been treated with high dose chemotherapy followed by stem cell rescue with or without consolidative IFRT from the CIBMTR database. A total of 244 patients with radiation pre-transplant, 76 with radiation post-transplant and 178 with no radiation pre or post transplant who underwent autologous stem cell transplantation in refractory or relapsed with Hodgkin’s lymphoma reported to the CIBMTR from 1990-2005 were presented. Plan to look at the radiation sites as part of the analysis. After voting, the Committee decided to defer the study for an additional fiscal year.

o. LY09-04: Outcomes of patients with non-Hodgkin’s lymphoma with pre-existing parenchymal CNS involvement treated with autologous stem cell transplantation versus standard chemotherapy and radiation therapy approaches (R Maziarz): Current status: protocol development. Dr Richard Maziarz presented the study. The specific aim is to perform a case match control study to compare the clinical outcomes between patients undergoing autologous transplantation with non-Hodgkin’s lymphoma with pre-existing parenchymal CNS versus patients with systemic non-Hodgkin's lymphoma with parenchymal involvement who were treated with radiation or chemotherapy only. The study will like to compare the outcomes of patients undergoing autologous stem cell transplantation with patients who are not treated with autologous stem cell transplantation with similar characteristics of disease. A subset of patients from our current approved study, LY04-03, >20 years of age underwent autologous bone marrow and/or peripheral blood stem cell transplants for non-Hodgkin’s lymphoma with pre-existing brain CNS involvement, from 1990 and 2005 will be compared to the CNS Lymphoma Collaborative Group report (n=113) in which represents 90% of patients who didn't undergo transplantation but rather received standard radiation or neuro-oncology therapeutic maneuvers (Doolittle ND, Abrey LE, et.al. Blood 2008; 111: 1085-1093). Dr Maziarz specified at last year’s Tandem meeting that statistician help from the Collaborative Group will be given. Plan to exclude cases with a subsequent autologous transplant.

5. Future/proposed studies
   a. PROP 1209-12 Outcomes of autologous stem cell transplant in HIV associated lymphoma (B Wirk). Dr Wirk presented the proposal. This study will like to determine the outcomes of autologous stem cell transplant for HIV associated non-Hodgkin lymphoma and Hodgkin lymphoma in first complete remission or relapse in comparison to a matched cohort of HIV negative lymphoma patients. The primary objectives of the study will be to determine the treatment related mortality, disease relapse/progression, progression free survival and overall survival. There are a total of 24 HIV positive cases only (NHL=15 and HD=4). Dr Sonali Smith exposed the problem with the study era. Dr Marcie Tomblyn explained the supplemental information that might be needed (i.e. heart) and the low response rate received. This supplemental information started in 2007. It was also mentioned the current EBMT and BMT/CTN on-going studies that overlaps these goals. After voting, the Committee decided to drop the proposal.
   b. PROP 1009-06 Outcomes of allogeneic stem cell transplantation for patients with chemorefractory aggressive non-Hodgkin’s lymphomas (M Hamadani). Dr Mehdi Hamadani presented the proposal. This study will like to describe outcomes with allogeneic transplantation for patients with chemotherapy-refractory aggressive non-Hodgkin’s lymphomas. There are 311 patients that underwent an allogeneic transplant for chemorefractory aggressive non-Hodgkin lymphoma reported to the CIBMTR between 1990 and 2007. The additional exclusions are: patients <18 years of age, cord blood, twin transplants and no previous autologous transplants. After voting, the Committee decided to accept the proposal.
c. **PROP 1209-18** Umbilical cord blood versus unrelated or related donor allogeneic hematopoietic cell transplantation for patients with lymphoma (V Bachanova). Dr Linda Burns presented on behalf of Veronika Bachanova. The study aims to compare the clinical outcomes between patients undergoing an allogeneic hematopoietic cell transplant from unrelated umbilical cord blood versus matched unrelated or sibling donor for non-Hodgkin’s and Hodgkin’s lymphoma and to determine patient- and donor-, disease-, and transplant-related factors associated with favorable progression-free and overall survival. EBMT has an ongoing study looking at the same idea and this study will validate theirs. Suggestions: distinguish between single vs double cord blood and will analyze CD34 cell doses. Would like to keep Hodgkin’s lymphoma in this study and analyze haploidentical transplants in a different study that can be proposed next year. After voting, the Committee decided to accept the proposal.

d. **PROP 1209-20** Outcome of patients with transformed non-Hodgkin lymphoma treated with autologous versus allogeneic transplantation (T Fenske). Dr Timothy Fenske presented the proposal. This study will like to look at 43 autologous and 22 allogeneic patients that underwent hematopoietic cell transplantation for transformed NHL reported to the CIBMTR between 1989 and 2007. EBMT has a 2001 study that looks at 50 transformed cases with an autologous transplantation. There was a consensus of merging LY09-01 with this proposal and include Dr Linda Burns as co-principal investigator since she proposed a similar idea years ago.

e. **PROP 1209-22** A comparison of the outcomes of autologous and allogeneic stem cell transplantation for patients with diffuse large B cell lymphoma or Hodgkin lymphoma refractory to first salvage chemotherapy but sensitive to second salvage (P Armand). Dr Philippe Armand presented the proposal. This study will look at 126 autologous and 54 allogeneic patients that underwent hematopoietic cell transplantation for patients with DLBCL or HD refractory to first salvage chemotherapy but sensitive to second salvage reported to the CIBMTR between 1995 and 2007. At the Committee it was suggested to go back to 1990 instead of 1995 and restricting to 2001. After voting, the Committee to drop the proposal.

f. **PROP 1209-28** Reduced intensity allogeneic hematopoietic stem cell transplantation in patients with mature T-cell NHL (M Delioukina). Dr Maria Delioukina presented the proposal. There are 82 patients that underwent a non-myeloablative allogeneic transplant for mature T-cell and NK T-cell NHL reported to the CIBMTR between 1995 and 2007. Half of these patients overlap with our current ongoing study LY06-05. After voting, the Committee to drop the proposal.

g. **PROP 1209-34** An updated comparison of allogeneic versus autologous hematopoietic stem cell transplantation for lymphoblastic lymphoma (A Chen). Dr Mahmoud Aljurf presented the proposal. One of the specific aims is to compare the overall survival after allogeneic vs autologous hematopoietic stem cell transplantation for lymphoblastic lymphoma in the modern era. There are 27 autologous and 115 allogeneic patients that underwent hematopoietic cell transplantation for patients with lymphoblastic lymphoma reported to the CIBMTR between 1997 and 2007. After voting, the Committee decided to accept the proposal.

6. **Other business**

Once studies in progress and proposals were discussed the Committee was asked to vote for proposals and studies LY09-01, LY09-02, LY09-03 and LY09-04.

No other business was proposed and the meeting was adjourned at 4:45 PM.
The following are the voting results:

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