1. Welcome/Apologies
   Apologies: Dr. J Jou, Dr. A Stephens, Dr. T George, M Brereton, Dr. H Hoffman, Dr. E Torlakovic, B Langley, Dr V Corrons, Dr Peng, B Wood

2. Attendance List is attached at the end of these meeting minutes.

3. Minutes of Nice 2012 Meeting - Approved

4. Published Projects (2012)
   a. ICSH recommendations for the measurement of HB A₂. IJLH. 2012, 34(1) 1-13
   b. ICSH recommendations for the measurement of HB F. IJLH. 2012, 34(1) 14-20
   c. ICSH recommendations for the identification, diagnostic value and quantification of schistocytes. IJLH, 2012, 34(2) 107-116

5. On-going Approved Projects
   a. Extended Differential Reference Method – B Davis
      Summary: Published in Cytometry what has been done to date comparing 3 methods
      Found no method to be perfect.
      This was not intended for routine practice, but vendors to use for validating WBC differentials on new analyser. Vendors voiced that it needs to become the recognized predicate method in North America for FDA acceptance.
      Needs to be published as a reference method.

      Next steps: Look at highlights from each of 3 methods and develop one sound method
      To have 8 colour panel to do full differential and validate with at least 4 sites around the world
      Will approach Wallace Coulter foundation for funding.

      Timelines: Request for funding to be submitted by April with update at next meeting.

   b. Hemoglobin Standard – B Davies
      Eurotrol questioned whether needed FDA clearance; clarification was asked to FDA. The response provided was not clear, but the interpretation is that the product can be brought into the US to be sold.

      Please write to Bruce if you aware of any issues.

      Product does not need to re-tested until 2013
c. Guideline for Validation of Automated Haematology Analysers – C Briggs / N Culp

Summary: Reviewed related CLSI documents and will send out a draft to be reviewed by December.
Incorporating a separate section on image analysis, determine what needs to be done for validations, taking into account validation requirements in countries other than US

Next steps: Draft to be distributed to stakeholders for comments
Determine what needs to be done for validations on cell image analysis

Timeline: Draft to be ready next meeting with gaps

d. Standardisation of Cell Morphology Grading – S McFadden/ G Zini

Goal of project: Eliminate unclear or ambiguous nomenclature
Eliminate non-useful grading

Summary: Outcome of nomenclature meeting sent to all panel members for comment, 50% responded at this time
Morphology grading for RBC and Platelet has been sent out for current practices in laboratory
Small group to look for background material
Panel group will be reduced to the members that respond by a set deadline

Next steps: Create a draft on nomenclature to be submitted to panel members, affiliations and vendors for comments.
To be submitted to UK-NEQAS, CAP, QMP-LS (Ontario), RCPA (Australia)

Timeline: Nomenclature based document to be circulated with tables to be discussed at next meeting
2nd phase: approach groups to have a pictorial bank for grading

Question: Is it possible to use mathematical algorithms from analysers to help standardization grading.
Answer: Possible next step; would have to be another study.

e. Validation of Cell Based Assays – B Davis.

Summary: FDA does expect that laboratories that develop assays to follow same guidelines as manufacturers. A guideline is to be published, but has not yet occurred
Purpose of this project is to create guidelines for flow based assays and Work started in March 2011
Document (72 pages) has been created and distributed for comments ICCS also part of the process.

Next steps: To be sent to Cytometry for publication, due to nature of guideline and will be a “first” special issue

Timeline: To be published in March 2013
f. **Sample Stability – Dr R Simon**

Summary: Final draft has been submitted for review

Discussion: Where to be published and if should be published as an ICSH document
No representation for North America which is a requirement
Study needs should include more samples and abnormal samples

Decision: Can be submitted to journal of choice (probably IJLH) but not as an ICSH guideline
Carol and Gina willing to provide a review if asked by the journal

g. **MPV Standardisation – Y Nagai / S Machin**

Summary: Presentation by Dr. Y Nagai
1. The variability of MPV measurement:
   - Time delay in the testing from time of venipuncture
   - Different automated cell counters using different technologies
2. A comparative study for optimizing the immune platelet reference method of platelet size using flowcytometer, phase contrast and a biological microscope

Suggest: Improve reference method by using specific sized beads
Investigation for standardization of platelet volumes scale
Proposal of standard based on the comparative study

Proposal: Nihon produces specific beads for the study of normalized platelet volume axis in the distribution curve to ensure microparticles have been excluded from the MPV determination
Propose to send out a set a size of 0.5 to 1.0 Um microparticles

Next steps: Dr Nagai to write a brief proposal for the distribution of the beads to be reviewed by Sam, then to be distributed for comments

h. **Standardisation of Bone Marrow Immunohistochemistry – E Torlakovic**

Summary: To create guidelines for the fixation and decalcification of bone marrow

Manuscript with results of the experimental phase and literature review is in preparation; the plan is to submit the paper for publication by the end of this year,

Discussion: First stage is not an ICSH initiative; the guidelines would then be under ICSH

Next step: Develop guidelines for optimal treatment of tissue to follow for submission by the end of March 2013.
Requested that a copy of manuscript be reviewed by Dr. Lee, Dr. Copeland and Dr. Proytcheva
i. **Guidelines for the Automated Counting of Body Fluids** – G Bournier.

Summary: Outline has been reviewed by panel members
First draft has been started.

Next step: Start first draft and distribute to committee for comments by end of year
Have first draft ready for Spring meeting, 2013
Draft to also be submitted to the appropriate vendors

j. **Peripheral Blood Film Review and Reporting by Physicians** - M. Proytcheva

Goal: 1. Develop ICSH guidelines for blood film review by a laboratory hematologist
2. Develop guidelines when a clinician can request a review by
   Hematologist/ technologist
3. What information should be provided by the hematologist in the review that would
   be clinically meaningful

Discussion: Survey has been distributed on current practices for review and reporting.
To date, 37 responses
Survey results to date show great variability in review practices and demonstrates
the need for guidelines.
Should include countries that do not have physicians/pathologists as
head of laboratories, such as Netherlands, Belgium and Germany

Next steps: Complete Data collection and perform analysis of the data
Expand the number of participants

Timeline: Spring 2013, complete data analysis
Fall 2013, final discussion
December 2013, final manuscript to be submitted to IJLH

6. **Potential New Projects**

a. **Standardisation of Test Performance Based on Clinical Need** – Dr. T Yu
   To be re-proposed at a later date.

b. **Standardisation of Haematology Reporting** – M Brereton/ K Hyde.

   Summary: Questionnaire on units used for a full blood count sent out to panel members
   Data to be analysed

   Discussion: on whether reference range should be included

   Next steps: Present report on summary of data to be presented at next meeting;
   Phase 2 would be reference ranges; to be discussed in May
c. Assessment of automated equipment for the measurement of HGB A2 – A. Stephens

Proposal: To look at the possibility of developing an Hb A2 standard
See Attached report.

Discussion: The need for an Hb A2 Standard

Next step: Dr. Stephens to look into the work being done by A. Mosco in Milan on a pure A2
To be discussed at next meeting

7. Further proposal of New Projects

a. Flow cytometric diagnosis and monitoring immunophenotypic and genetic features
   Chair: Wolfgang Kern
   - Need for clarification for use of flow in myeloid malignancies
     o Standard panels used in labs not practical or reasonable
     o Inter-lab heterogeneity in diagnostic approaches in data evaluation and reporting
     o Difficulties for clinicians to interpret and weight flow reports
     o WHO lists typical, but flow labs faced with a set of differential diagnosis

   - Aim: parameters to establish diagnosis of AML, flow features of subgroups, MRD detection and strategies for follow-up analysis, diagnosis of myelodysplastic syndrome, parameters typically displayed in myeloproliferative neoplasm.

   Project plan: Form expert panel
                  Decide guidelines
                  Prospective application and validation in expert labs
                  Publication in scientific journal

   Timeline: 3 years, guidelines to be done sooner, but time required mostly for the application in the expert labs
   Costs: travel and logistics for yearly meeting

Discussion: Subject very broad and if should be separated into several projects
   3 years is a long timeline and technology could change over this time, and should be updated with new technology
   Already groups formed and publications coming out, including WHO
   Could EuroFlow be incorporated into this project although it was noted that EuroFlow has become a commercial entity
   ISCH guideline could be published as an alternate to EuroFlow
   Question whether could the different projects, but prioritization may be a challenge

Decision: Initial stages of project to involve Bruce Davis, Dr Zini, Dr. Han and Dr. Prytcheva
Industry involvement: Beckman, BD, Nihon Kohden

Dr. Zini to write a response to Dr Kern to be distributed to the above, board members
   Raised by Nigel Llewellyn-Smith
   Presented by Dr. S Machin

   Aim: Provide: 1. Reproducibility
   2. More reliable method to report the true biology of the immature platelet

   To Date: Dr. Machin has contacted vendors for support

   Next steps: Need a panel to develop a protocol and a costing regimen

   Proposal: Meet to discuss next steps with interested parties at 8:30 Friday morning

c. Guidelines for critical value reporting – Dr. T George
   To be deferred to spring meeting

d. Standardization of G6PD testing – K Hyde
   A review was presented on the type of screening tests and assays, the temperature and if whole blood is being used.
   Survey did show that there is variation in screening, terminology, temperature of assays, WBC removal and reference intervals.

   Next steps: Determine whether need more data on survey
   Consider if there is a need for a guideline

e. Basic diagnostic procedures for Hemolytic Anaemia – Dr J Hin
   Propose: Develop new testing algorithms with new test parameters and the differentiation from other anemias
   Develop team from ILSH, KSLH, and ANCLS

   Next steps: Present a formal proposal at next meeting

8. Relationship with Other Professional Bodies

   a. ISLH
      a. Current challenges to work with ISLH on holding of meeting
      b. Will have a session at the conference and one breakfast session
      c. Meeting in Brazil and one to be held in China
      d. Dr. Proytcheva was invited to speak at Brazil on the work of ICSH. To be presented by S Meade on behalf of Dr Proytcheva due to visa issues. (See attached)

   b. ISH – no communication, but will respond to if receive any correspondence

   c. CLSI – invitation will be given to attend the meeting in Toronto and discuss if any joint ventures

   d. JCTLM – new representative, Dr. Thomas Nebe. Will be invited to next meeting and present an update on projects
e. IJLH – Impact factor has dropped. IJLH is looking at new strategies. Some of the articles could be published as letters. Need to tighten up on the acceptance of articles. Impact will be seen in about 2 years
Proposal to have a meeting at the next ICSH meeting in England
Have appointed associated editors that are experts in the field
Suggest that members of ICSH try to submit an article
ICSH guidelines are available for free download from the journal

f. WHO Report – Request was received by Dr. Gaby Vercauteren Sept 12th looking for an immediate response to the potential of collaborative projects. WHO has asked for ICSH to perform a specific comparison on POCT which is beyond the scope of ICSH.
There is a proposal to link the nomenclature project to the work done on the Digital Morphology – the Peripheral Blood Gallery presented at the May meeting
Keith Hyde to respond that POCT is beyond our scope and to extend an invitation to attend an ICHS meeting to make a proposal to link the morphology gallery; work is on-going,

g. JSLH – Membership is increasing
Group is very active in discussions for criteria on standardization that will be clinically useful

h. CCS - Extended Differential project has been completed and published in Cytometry.

i. CAP - Bruce Davis brought up an issue with proficiency testing on hematology instruments on using commercial material opposed to making an "unknown" material
Discussion to be help at next ICSH develop a guideline on the testing material to be used for proficiency testing. To be included any representatives of the different proficiency programs

j. IFCC – Sam will contact the president (Dr G. Beastall) about collaboration on standards

k. Wallace Coulter Foundation – B Davis will be contacting for funding. Meeting may be held in China

l. NCCL - National Center for Clinical Laboratories (China) – ISLH will be very happy to support their initiatives. Contact: Dr. M Peng

9. Date of next meeting - provisional
May 9th, meeting in Toronto providing a conference and hotel rooms available
Discussion took place whether to hold meeting May 24, 25 in Milan at IFCC meeting
Opportunity to get presence known
Sam to contact the president on opportunity

10. Autumn meeting
Proposed to be held in Gerrards Cross (15 minutes from Heathrow)
Provisional date: 7th/8th October (Monday/Tuesday), Beckman has agreed to help sponsor

Other business
Thank you to Sysmex for hosting the meeting and the dinner
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