Strengthening Medical Laboratory Services in the Caribbean*

3rd Standard Methods Drafting Group Meeting

16 – 20 October, 2006

Joseph’s Restaurant, Maraval, Trinidad

Report prepared for the Project Management Unit
Caribbean Epidemiology Centre

*A CARIFORUM project funded by the European Union
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Abbreviations:

CAREC  Caribbean Epidemiology Centre
CSLI    Clinical and Laboratory Standards Institute
CLAS    Caribbean Laboratory Accreditation Scheme
SOPs    Standard Operating Procedures
QMPLS  Quality Management Program – Laboratory Services (formerly NCCLS)
CCH II  Caribbean Cooperation in Health II
CCH III Caribbean Cooperation in Health III
CSME    Caribbean Single Market and Economy
CSM     Caribbean Single Market
CROSQ   CARICOM Regional Organisation for Standards and Quality
CPA     Clinical Pathology Accreditation (UK) Ltd
MOU     Memorandum of Understanding
NAFP    National Accreditation Focal Points
UWI     University of the West Indies
ROYTEC  Royal Bank Tertiary Education Centre
UTEC    University of Technology
BCC     Barbados Community College
CKLN    Caribbean Knowledge and Learning Network
CARIFORUM Caribbean ACP states
OCTs    Dutch and English Overseas Countries and Territories
NLACs   National Laboratory Advisory Committees
MLT     Medical Laboratory Technologist
SWEDAC  Swedish Board for Accreditation and Conformity Assessment
EQA     External Quality Assessment
HPA     Health Protection Agency
CRMC    Caribbean Regional Microbiology Council
CAP     College of American Pathologists
NCCLS   National Committee for Clinical Laboratory Standards (now CLSI)
ESBL    Extended spectrum beta-lactamase
A European Union funded Project

Strengthening of Medical Laboratory Services in the Caribbean

Laboratory Management System Advisory Committee
Microbiology Standard Methods Drafting Group Meeting

October 16th – 20th, 2006
Joseph’s Restaurant, Maraval, Trinidad

Agenda

Meeting Objectives

- To familiarize members of the Microbiology Standard Methods Drafting Group with the CAREC “Strengthening of the Medical Laboratory Services in the Caribbean” Project context, objectives and major strategies
- To agree on terms of reference for the Microbiology Standard Methods Drafting Group
- To produce a package of Standardized Operating Procedures as defined by the 2nd Microbiology Advisory Sub-Committee

Terms of Reference for 2nd Microbiology Advisory Committee Meeting

- Agree on a format for standardized SOPs
- Produce packages of a number of prioritized standard methods, as defined by the 2nd Microbiology Advisory Sub-Committee
- Initiate the process for the standard methods framework
- Develop the strategies and plans for translating the recommended model into practical and acceptable solutions for the Microbiology systems of the region
- Undertake any relevant tasks

Monday 16th October, 2006
8:30 REGISTRATION
9:00 Welcome, Introduction, Agenda Overview & Meeting Objectives
Ms. Julie Sims – Laboratory Technical Specialist – CARIFORUM SMLS Project

SESSION 1 - REVIEW

9:30 Feedback from Standard Methods Working Group / Review of Previous Meeting
Feedback and Questions
Ms. Julie Sims

10:30 BREAK

SESSION 2 – OPERATIONALISING THE GROUP

10:45 Formation of Working Groups
Structure of Working Groups
Time Frames
Ms. Julie Sims

SESSION 3 – STANDARDISING METHODS

11:15 Standardising Methods – Group Work

12:30 LUNCH

2:00 Standardising Methods – Group Work

Tuesday 17th October, 2006

8:30 Review of Day 1 – Ms. Julie Sims
9:00 Standardising Methods - Group Work
10:30 BREAK
10:45 Standardising Methods - Group Work

12:30 LUNCH

1:30 Standardising Methods - Group Work
3:15 BREAK
3:30 Standardising Methods - Group Work

Wednesday 18th October, 2006
8:30  Review of Day 2 – Ms. Julie Sims  
9:00  Standardising Methods - Group Work  
10:30  B R E A K  
10:45  Standardising Methods - Group Work  
12:30  L U N C H  
1:30  Standardising Methods - Group Work  
3:15  B R E A K  
3:30  Standardising Methods - Group Work

Thursday 19th October, 2006

8:30  Review of Day 3 – Ms. Julie Sims  
9:00  Standardising Methods - Group Work  
10:30  B R E A K  
10:45  Standardising Methods - Group Work  
12:30  L U N C H  
1:30  Standardising Methods - Group Work  
3:15  B R E A K  
3:30  Standardising Methods - Group Work

Friday 20th October, 2006

8:00  Review of Day 4 – Ms. Julie Sims  
9:15  Standardising Methods - Group Work  
10:30  B R E A K  
10:45  Presentations and Feedback – Plenary Session  
12:30  L U N C H

SESSION 4 – OPERATIONALISING OF DRAFTING GROUP

1:30  Individual Roles within the Group – Plenary Session  
3:15  B R E A K  
3:30  Wrap Up and Next Steps – Ms. Julie Sims
1. Welcome

Ms. Sims opened the meeting, welcoming the participants and noting the presence of Ms. Jocelyn Joseph-Thomas, an experienced writer of standard methods, who would be observing and contributing to the work of the meeting.

Following participant introductions, Ms. Sims expressed the hope that in addition to the projected writing of new Standard Operating Procedures (SOP's), time would permit participants to review the technical work done in the 2nd meeting of the Drafting Group, the goal being to get the SOP's circulated by the end of the Project in mid-December. Two editors are engaged in the process of checking them for correctness and to ensure that the methods used in them are validated methods. The first editor has begun this work already and the second editor is to review it. Ms. Sims indicated that she intends to launch the SOP's as a finished product, for reasons of document control. She reminded the participants of the importance of knowing where every copy of your documents is at any point in time and the importance of document control for the accreditation process. However, she indicated that participants could photocopy individual pages if they wished. She expressed agreement with Mr. Khan’s suggestion that the SOP on writing SOP’s could be circulated, as it could support the writing of new SOP’s. The final version of the SOP’s would be ready for circulation in two months and a graphic designer has already begun work on them, and they will probably be issued on a CD and a small number of printed copies will be made available.

Ms. Sims then reviewed the objectives for the meeting, the expected outcome being the production of 3 SOP's to support the technical SOP's in the following areas:

1. Health and Safety
2. Quality Control
3. Media

She indicated that the basic safety SOP would not take the place of the Health and Safety manual, but would simply support the technical SOP's. An SOP for tests to describe the Quality Control of reagents and provide Pro-formas for this is necessary, as this is generally not covered in the Caribbean or if it is being done, it is not documented. There are usually only sterility checks. She indicated that work might be done on anti-microbial susceptibility testing, as well as on how to ensure that everyone in the region is using the methods.
SESSION 1: Review

2. Standard Methods Working Group Meeting

In her presentation, which forms Appendix 1, Ms. Sims reviewed the purpose, objectives, terms of reference, agenda and the main outcomes, recommendations and implications of the meeting. She highlighted the following:

- The mandate of the Standard Methods Working Group came from the Microbiology Advisory Sub-Committee - to develop SOP’s for the region
- Some of the participants of the first Standard Methods Working Group of 9-11 August 2005 are participants in the present meeting
- Regional SOP’s should contain a variety of validated methods, as a variety of methods is used throughout the region.
- There should be SOP’s for all levels of lab service
- National SOP’s contain a definitive minimum standard which is then graded to the level of service provided by the particular lab
- The production of the final version, ratified by the Regional Microbiology Committee, would take one year
- The process needs to be incorporated into the National Strategic Plan in order to ensure continuation of its funding and development. The cost benefits of the programme must be made evident.

3. Feedback from the 2nd Standard Methods Drafting Group Meeting

In introducing the feedback, Ms. Sims explained that as the anticipated time taken for a regional SOP to be produced, ratified and circulated was a year, it was decided to short-cut the process and to benefit from the availability of funding from the Project to produce some technical SOP’s at this meeting. These would also have evidentiary value in the pursuit of further funding, as well as assisting labs to use validated methods and assisting them with their documentation and the training of their staff.

17 SOP’s were produced at this meeting and reviewed by Ms. Sims for format, content and additional work. Ms. Sims drew attention to the recommendations emerging from this review, highlighting in particular that:

- "Title" and "Purpose" require standardization
- The Introductions require some expansion
- The link between the SOP’s and the Appendices needs to be established e.g. genital specimens were being processed in different ways and there was no indication as to why they were being classified the way they were classified
- Specific safety and rejection criteria must be included
- The flow chart should be completed before the writing of the SOP. International conventions on the symbols used on the flow chart should be followed, so that some statements made in the diamond-shaped boxes would have to be adjusted to form questions, as that shape is conventionally used for questions
- There should not be reference to SOP’s of other organizations or to non-existent SOP’s
- It is important to read and use the material supplied in the binders
- If the HPA methods are to be used, they have to be used in their entirety. A single sentence from the HPA cannot be used.
All methods have to be evidence-based and validated methods.
As these are regional methods, not local ones, methods should be included for a variety of lab situations e.g. labs with and labs without resources.
Only published and validated methods should be used for the meeting, in the interests of speed of production and because local methods are generally not validated ones.

This presentation forms Appendix 2.

4. 3rd Standard Methods Drafting Group Meeting

After summarizing the achievements to date, Ms. Sims introduced the SOP’s to be produced at the current meeting, stressing that:

- There is a need to produce an SOP on how to maintain a stock of working organisms for Quality Control and create a proper repository for them, as most people do not have the relevant procedures for all of the vast number of organisms used.
- For the production of the Media Preparation SOP, the technical SOP’s should be reviewed, so that all media used in them are included in this SOP.
- The work listed in her presentation would be collated into 3 support SOP’s i.e. Media and Media QC, Test and Reagent QC and Safety.
- Since the networking did not go well in the period between the 2nd and 3rd meetings, there is a need to make a definite plan for this to function properly in the future.
- In answer to Mr. Burke’s inquiry as to why serology has not been included, Ms. Sims explained that the Steering Committee of the Project, as well as the lab directors, specifically requested work on Bacteriology, as this is a labour-intensive area where equipment and QC are needed and, for example, culture, isolation and anti-microbial testing are done. Chemistry tends to have up-to-date equipment in the region but microbiology is somewhat lacking in basic equipment on the whole. Also serology can draw on the funds assigned to HIV research which are plentiful.
- Any further work, such as work on mycology as Mr. Burke would like to see done, would have to be funded by another agency. Also, most laboratories do basic enterics and urine cultures, for example, and few do mycological investigation. The reference lab for mycology is still a Texas laboratory. Ms. Clarke of CAREC indicated that she is seeking funding for a workshop to be held in March 2007 on mycology.
- Most of the funding for HIV at present is for detection and research. It will be important to seek ways of tapping into this HIV funding in order to finance work on microbiology support for HIV treatment. A proposal for this should be brought to the Regional Microbiology Committee Meeting before the end of the year.
- A funding agency for the development of Chlamydia testing is also needed.

This presentation forms Appendix 3.

Ms. Kellier commented that the Western Regional Health Authority in Jamaica has put in proposals to agencies supplying HIV funding and the Cornwall Regional Lab has received funds for things such as microscopes, furniture and TB testing which are relevant to HIV.

SESSION 2: Operationalising the Group

The working groups were then formed as follows:

Group A Safety

Rayaad Khan
Anthony Bayley
Zobida Khan Mohammed

**Group B  Media**

Gail Trotman
Heather Wint
Alexis Wilson Pearson
Valerie Levy
Norman Burke

**Group C  Tests & Reagents**

Adriene Kellier
Allison Scavella
Solitaire Parra Maza
Sonia Edwards
Astrid Dirksz
Jocelyn Joseph

**Group D  Propagation & Maintenance of QC Organisms**

Monica Pollard
Martin McKenzie
Juliana Applewaite
Denise Clarke

**Revision of the method SOP’s**

Zobida Khan Mohammed
Juliana Applewaite
Norman Burke

Draft copies of the SOP for an SOP and Quality Assurance in the Microbiology Laboratory were then distributed and work began on the SOP’s.
SESSION 3: Standardising Methods

5. Group B Media

Some points which arose in discussion were:

- Ms. Wint made the point that in Jamaica some labs make up their own transport media. In Barbados swabs come with the media made up already.
- Ms. Wint suggested that KIA is used for stool and TSIA for others. Mr. Burke indicated TSIA for stool.
- Baird-Parker for Staph, Tinsdale substitute to do Albert's stain, an egg medium such as Loflers, Sorbitol-MacConkey for E.coli, Rabinose, TBA, TSIA, KIA, MIL and Arizona for Shigella were discussed.

6. Group A Safety

The group plans to adopt an introduction from the CDC book. They worked on “Scope”, using the wording “as recommended by regional laboratories. It may be adopted or adapted by any laboratory as needed”. “Hazards” were placed before “Personal responsibilities”. Re “Terms and definitions”, terms were selected from ISO 15190 and risk group classification was adopted from ISO 15190 also. The group waited for Mr. Bayley’s input to decide whether to put in a management section. Biosafety levels were taken from “Identification of Hazards”, p.3 and 9 Numbers 8, 9 and 10. Personal responsibilities from p. 10, number 11. Immunization status comes under “Personal Responsibility” p. 10. PPE p.11 includes everything inside and outside the lab. Emergency showers, first aid kit and good housekeeping practices – p.40. Special requirements for aerosols are dealt with separately and should be included. There should be reference to the manufacturer’s instructions. Chemical safety should be included – p.17. Only elements relevant to Microbiology will be used.
7. **Group D Propagation and Maintenance of QC Organisms**

The group inquired of all participants whether anyone stores cultures in Nitrogen tanks. Only in Barbados is this done so the group decided to place it as a note/option under “Safety.”

8. **Day 3-4 Wednesday and Thursday, 18-19 October 2006**

Ms. Michelle Lucas Nurse replaced Ms. Clarke and Mr. Jawaherlal Mewahlal joined the workshop, working with Group A.

9. **Review**

Groups completed their work on the SOP’s and in the final plenary session, reviewed and amended all the SOP’s produced, including the additional SOP on abscesses and post-operative wounds, deep-seated wounds and tissue biopsies prepared by Ms. Applewaite. The following points were made in discussion:

- The use of plates with half pure agar and half blood on top may or may not be a validated method but it gives better haemolysis and is helpful in places where there is a shortage of blood. It is certainly better than other measures used in such circumstances e.g. the use of out-dated blood from the blood bank or TSA with no blood in it.
- New York City and Sabouraud should be used for vaginal swabs. The majority of labs do a wet prep, a Gram stain and use Thayer-Martin(TM) alone, thereby inhibiting the growth of GC. TM grows yeast after 24 hours.
- 40-50% of Trichomonas is lost in a wet prep, compared to doing them in a broth.
- Litmus paper does not work well with coloured media. It can be used with clear media.
- The work assigned to Group D was challenging because the information required was not available from a single source.
- There was discussion on the danger represented by prions, indestructible organisms spread in hospitals, which have come into existence as a result of the practice of feeding offal to cattle. These organisms have a long incubation period and are responsible for some deaths among young people and some deaths previously attributed to Alzheimer’s disease. It is also thought they may be spread through blood transfusions. Even when put through 4 cycles of the autoclave process, these organisms do not die. As a result, eye operations, for example, have become high risk.
- CCDA agar is designed to be incubated at 37°C and a 42°C incubator is no longer needed. Growth is better in CO². However gas packs are better; there is more contamination in CO².
- The use of a split air-conditioning unit in the microbiology lab was discussed. The airflow should be checked with the air-conditioning unit on. There should be a cutout switch on the outside of the building. If a positive culture is dropped, staff should leave the room and the unit should be switched off from the outside. Any Category 3 room should be smoke-tested for leakage. However, the cost of the upgrading of the room for safety is prohibitive.
- As Group A recommended in their SOP, there should be a designated safety officer in every laboratory.
- A Biomedical Waste Disposal guideline is to be included in the SOP.
- A programme should be done for visitors and people coming to work in the laboratory, to raise awareness of basic hazards and risks. The visitors should be required to sign to indicate that they have read and understood these. A list should be kept of all people coming into the department who are not a part of it. They should be signed in and out, an important requirement for head count.
- Mr. Bayley has literature on new techniques for compounding waste employed in Japan.
The purchase of a nanometer to check the airflow of the hood of the bio-safety cabinet was recommended. Type 3A has an alarm set to alert if the airflow goes beyond where it is supposed to be. If the airflow is being checked, the people who normally sit in front of it should be in place during the checking.

Some dangerous Category 3 organisms which should be dealt with under a hood are being checked on the bench in some Caribbean labs.

Mr. Burke extended thanks on behalf of the participants to Ms. Sims and the support staff for their input into a rewarding meeting and Ms. Sims indicated how pleased she was with the work done, as to her knowledge this is only the second time a region is doing such work. She added her thanks to those of Mr. Burke to the support staff.
SESSION 4: Operationalising of Drafting Group

10. Final decisions on networking, timelines and topics for further work

It was decided to submit the 17 SOP’s completed in the 2nd workshop and the 4 undertaken in the 3rd workshop to the editors and graphic designers. For completion of these and for ongoing networking to sustain the process of creating SOP’s, it was decided to organize the groups around 4 countries. The overall coordinator of the network would be **Juliana Applewaite**. The groups would be as follows:

**Trinidad**

**Anthony Bayley** (Coordinator), Zobida Khan Mohammed, Jawaheerlal Mewahlal, Denise Clarke, Michelle Lucas Nurse, Monica Pollard, Shirematee Baboolal, Ashok Rattan, Eliott Samuel

**Jamaica**

**Rayaad Khan** (Coordinator), Adriene Kellier, Valerie Levy, Heather Wint, Norman Burke, Ede Tyrrell-Langevine, Alexis Wilson Pearson

**Barbados**

**Juliana Applewaite** (Coordinator), Edmund Blades, Gail Trotman, Martin McKenzie, Sonia Edwards

**Dutch Antilles/Curacao**

**Allison Scavella** (Coordinator) Astrid Dirksz, Osric Wanga, Helga Leito, Solitaire Parra Maza

Topics for future work would be:

1. Abscesses (Dutch Antilles/Curacao)
2. Blood culture (Jamaica)
3. Anti-microbial Susceptibility Testing (AST) (Trinidad)
4. Superficial wounds (Barbados)

Deadline for the submission of the first draft of the work – **End of January**. At the end of every month, coordinators will communicate with each other and with the group to ascertain progress.
Ms. Sims reminded participants to send the results of the media comparisons to her. Inquiries were made about getting New York City at a reduced rate if it is ordered as a region. Final comments by participants on the meeting were:

- An excellent meeting
- Each meeting gets better
- This meeting will make the job easier
- Pleased with the final product and its quality. Looking forward to seeing the finished product
- Techs can write! Appreciated the emphasis on teamwork in the meeting
- Great meeting. Thanks to everyone
- A tremendous week. Hope we maintain our QC alive. Can CAREC send us live strains? We cannot run out of QC media
- Control stains have been an area where work was needed in my lab. From next week will be implementing some of what was learnt in this forum
- We have to disseminate the knowledge acquired here. We have a wealth of knowledge – let us use it.
- A great week
- Very appreciative. Thanks to Ms. Sims for the invitation to attend. What we did helped me. It shows what we can do when we put our heads together
- Fantastic programme. It strengthens the labs in the region. We worked as a team and learnt from each other. We can share it with others at home, as I did after the last meeting when I presented to all techs in the department on format and standardizing of methods and gave them a copy of the format for SOP’s. Thanks to Julie and the administrative staff
- A great week. The production of the SOP’s will make the challenge to write SOP’s easier
- Remembering my comments after the first meeting, I have to say it met my expectations after all

Ms. Sims promised to recommend to CAREC that they should have a freeze-drier and maintain a stock of EQA organisms which they would distribute throughout the region, as everyone has problems obtaining and maintaining organisms. After extending warm thanks to Ms. Stephens for the time and effort expended on the workshop, she promised to remain in touch with the group beyond the life of the Project.

Margaret Hunte
Trinidad, 21 October 2006