

# RELAUNCH OF NATIONAL STANDARD METHODS

7<sup>TH</sup> FEBRUARY 2006

## FUTURE DIRECTION

### 1. Summary of recommendations

#### 1.1 What we are already doing

- Assign individual small groups to develop/update documents
- Collaborate with other professional groups
- Develop syndromic list for virology
- Design telephone audits, ask simple questions such as:
  - Do you apply National Standard Methods (NSMs) in full?
  - Do you extract parts relevant to you from NSMs?
  - Which parts do you not use and why?
- Invite laboratories to inform Standard Methods Working Group (SMWG) whenever they see a need for change of any method
- Improve website and the rate of downloading

#### 1.2 Actions underway

- Spend less time on BSOPIDs and BSOPTPs by increasing the review period to three years
- Offer Continuous Professional Development (CPD) points to participants in consultation process
- Remind participants by e-mail how much time is left of the consultation period (one month, two weeks, one week)
- If major changes are not made to the documents indicate on the website that no changes have been made
- Highlight/underline/italicise changes that are made to the earlier documents or type them in colour, and add the summary of changes at the front of the documents
- Make the front page easy to download

- Ask laboratories if they have Standard Operating Procedures (SOPs) not covered by NSMs and request copies
- Increase use of e-mail in development of documents
- Add a generic statement to all methods along the lines that resources and infrastructure are required to provide appropriate specimens to the laboratory in a timely fashion and to deliver/respond to reported results
- Contact all laboratories and ask for an individual who can take responses and feed back to ESL. This must be done while asking them what they want from us and by outlining the CPD and Clinical Pathology Accreditation (CPA) benefits of the process

### 1.3 Future actions to discuss at the next meeting

- How do we arrange/fund evaluations to provide minimum sensitivity/specificity data - role of MiDAS and prioritisation of evaluations?
- Use videoconferencing for some meetings
- Link to QC reagents and evaluation
- Link to National Programmes, Governance and clinical needs
- Develop syndromic list for bacteriology
- Develop detailed spreadsheet checklist for laboratories to audit compliance, the data could be collected and analysed centrally if in standard format. These would need to be tailored for each method. Reasons for non-compliances in audit may be very useful to indicate problem areas, availability of new methods etc
- In addition to telephone audits, design a brief, written audit that focus on problem areas highlighted by the telephone survey that take little time to complete
- Increase interactions with other working groups carrying out similar work to cut down on duplication of effort, and to raise profile, funding etc. NICE, Healthcare Commission, British Heart Association, national programmes and DH should be considered
- Methods are used internationally – consider invitation to members of international groups (ASM, CLSI, CEN, ISO, DIN, SFM, ESCMID, ECDC, WHO) to sit on the SMWG meetings and visa versa
- More flowcharts are needed for use on the bench
- Consider adding an ‘executive’ summary section to each SOP [‘For Commissioners’?] that summarises in non-technical language in a few sentences on what the SOP is aimed to achieve and why it is important to individual and public health that the work is done, and to this standard

- Move in to the following areas:
  - Molecular suites, chip technology, array technology, automated systems
  - Near patient testing (use of tests in primary care)
- Might it be possible to link into the results gained through clinical audits?
- How could the NSMs be linked to commissioning process?
- Clarify if the NSMs recommend a good minimum standard or the best practice?
- Standard Methods Working Groups should take the lead on development of the clinical guidance and clinical manuals for medical doctors and clinical scientists
- Production of documents for specific patient groups should be considered

#### 1.4 What we could do but need extra resources

- Publish NSMs in different formats including documents for introductions, flowcharts, algorithms
- 'Accredit' laboratories that use methods compatible with NSMs
- Develop pre- and post-analytical algorithms (discussions with AMM and primary care group already underway)
- Interpretative guidance (as important as SOPs)
- Set time lines for processing samples and identify which samples are appropriate
- Consider the implications of removing cell culture as a diagnostic test
- Involve health economists

## 2. Notes from Meeting

### 2.1 Morning session

Brian Duerden welcomed the members and representatives of professional organisations to the meeting (see Appendix 1). He presented a brief history of the National Standard Methods (NSMs) in the last 10 years and explained that the specific purpose of the current meeting was to brain storm and discuss the future direction and development of NSMs. A presentation was then given by Valerie Bevan on the development of NSMs, usage, achievements, and issues related to NSMs. This was followed by a presentation on Virology Standard Methods by Ken Mutton. Bharat Patel then gave a presentation on strategies for improving the future of National Health Services. After presentations, discussions took place on the following points:

- Increased reliance on molecular methods
- Near patient testing
- Chip technology
- Array technology
- Need for frontend algorithms

### 2.2 Afternoon session

The afternoon session started by dividing the audience into the following four groups to discuss questions that were distributed electronically prior to the meeting :

Group 1 Bacteriology review	Chaired by Secretary	Jacki Watts Azra Pachenari
Group 2 Virology review	Chaired by Secretary	Jim Gray Sam Gillanders
Group 3 Bacteriology future	Chaired by Secretary	Derek Brown Christine Walton
Group 4 Virology future	Chaired by Secretary	David Brown Clare Harris

(see Appendix 2 for the list of questions)

#### 2.2.1 Group 1 Bacteriology Review

Question 1 - Do NSMs continue to be fit for purpose?

Comments from group 1:

- The introductions are useful for education and training purposes
- NSMs set standards for training
- NSMs are not bench documents
- NSMs give confidence to users from an accreditation point of view
- NSMs reduce need for local evaluations

- The flowcharts are used on the bench and are needed more
- BSOPs are good support documents for what should be undertaken practically
- Laboratories use selected parts of the NSMs and acknowledge the HPA
- Laboratories need to add local kits etc to convert them to working documents

Question 2 - What do NHS users want from NSMs?

Comments from group 1:

- They want them as reference guides
- They want them for bench marking
- They want them up to date
- They are useful because it is a CPA requirement to have SOPs, and NSMs save them from writing their own from scratch

Question 3 - What can we stop doing?

Comments from group 1:

- Spend less time on BSOPIDs and BSOPTPs and do not reissue them unless a major modification is made

Question 4 - What can we improve?

Comments from group 1:

- Make the NSMs easier to download
- Reduce the length of introductions and examination procedures
- Produce guidelines for post analytical reporting
- Frontend algorithms will be useful for BMSs
- Pull out the bench sections into separate documents, produce a shorter form of NSMs as well as their current form
- Add a column on the website to state that no changes are made or put an asterisk on the issue number to show that no changes are made
- Highlight changes that are made to the documents and add the summary of changes at the front of the documents
- Increase the review period to three years

Question 5 - How can we encourage all laboratories to participate in the consultation process?

Comments from group 1:

- Offer CPD points to participants or send them certificates
- Send e-mails to people and mention how much is left of the consultation period (one month, two weeks, one week)

## 2.2.2 Group 2 Virology Review

Question 1 - What do NHS users of the NSMs want?

Comments from group 2:

- They want documents that are validated
- They want documents that are evidence based
- They want methods that are cost-effective
- The methods need better links to QC reagents, Evaluation, national programmes and clinical needs

Question 2 - What can we stop doing?

Comments from group 2:

Review of existing /well established methods

Question 3 - What can we improve?

Comments from group 2:

- Organise small expert groups to work on specific documents
- Have audit system
- Add evaluations to provide minimum sensitivity/specificity data
- Improve input from hospital laboratories
- Link to clinical governance
- If the document is established apply longer review period; If the document has changed apply shorter review period

Question 4 - How can we encourage all laboratories to participate in the consultation process?

Comments from group 2:

- Review should be a CPA requirement
- Offer CPD points

## 2.2.3 Group 3 Bacteriology Future

Comments from group 3:

Question 1 - What are the new demands?

Comments from group 3

- Changing environment and pressures in laboratories
  - Organizational changes
  - Increasing financial pressures
  - Increasing workload
  - Limited/less skilled staffing
  - Pressure for more rapid tests – reduced turn around times / 24h working
  - Increasing demands for data for epidemiological and financial purposes

- Need to ensure that methods respond to clinical / patient demands
- New scientific/technical requirements for laboratories
  - New methods needed to help cope with pressures e.g. automated systems run with less-skilled staff
  - New methods must have scientific/clinical benefit e.g. rapid screening for MRSA
  - New systems needed to extract data automatically e.g. systems that can generate data to meet routine surveillance requirements without input from laboratory staff

Question 2 - What are the future priorities for Standard Methods?

Comments from group 3:

- Maintain/update existing Standard Methods
- Improve input from user laboratories
  - Pressures on time mean laboratories do not give this a high priority
  - Make it easier to respond - highlight changes in drafts and give more detail in list of changes in re-issued documents
  - Invite laboratories to inform SMWG whenever they see a need for change of any method (wishful thinking?)
- Methods are used internationally – can the burden of development be shared? Consider ASM, CLSI, CEN, ISO, DIN, SFM, ESCMID, ECDC, WHO, others? May be difficult to organize with national differences/prejudices.
- Possible development areas
  - Automated systems?
  - Molecular methods?
  - Rapid tests?
  - Near-patient testing?
  - Ask laboratories if they have SOPs not covered by NSMs?
  - Evidence that Standard Methods result in better performance?

Question 3 - How should we move forward in the next 10 years to molecular methods?

Comments from group 3:

- Methods should be of proven clinical value, technically reliable and have adequate sensitivity and specificity
- Value of rapid tests are reduced unless specimens are transported to laboratories in a timely manner and processed promptly (pressure for 24/7 working as in other disciplines), results promptly returned to clinicians, and clinicians are able to respond to rapid results
- Examples of possible areas of application
  - Rapid screening for MRSA currently being assessed
  - Slow-growing organisms (e.g. Mycobacteria established)?
  - Detection of difficult/non-culturable organisms (e.g. fungi)?
  - Rapid identification?
  - Direct identification from specimen (STD, faeces?)

- Methods should be widely applicable and not dependent on specialist personnel
- Wide application requires development of commercial systems (standard method cannot be applied to commercial systems)

Question 4 - Should we be developing 'front end' algorithms that advise on which investigations to do in particular clinical settings?

Comments from group 3:

- Would be useful
  - To explain to clinicians why tests are necessary
  - To influence sources of finances (PCT, Hospital Trusts, DH) by recommending which specimens should be taken
  - To drive more appropriate clinical activity
  - To ensure that appropriate specimens are taken to meet surveillance requirements
  - To laboratories/Trusts/Commissioners of healthcare when specifying performance standards from the private sector
  - To provide authoritative laboratory input to protocols being developed by clinical specialist groups
- Already done locally to some extent in some laboratory handbooks
- Difficulties
  - Not just within laboratory remit
  - May be no "correct" advice on which investigations are appropriate in some situations
  - Range of other specialist groups are producing guidelines – interdisciplinary approach needed to ensure that guidelines from different sources are compatible.
- Suggested action
  - Consider adding a generic statement to all methods along the lines that resources and infrastructure are required to provide appropriate specimens to the laboratory in a timely fashion and to deliver/respond to reported results.
  - Consider adding an 'executive' summary section to each SOP ['For Commissioners'?] that summarises in non-technical language in a few sentences on what the SOP is aimed to achieve and why it is important to individual and public health that the work is done, and to this standard.
  - Centralised development of pre- and post-analytical guidelines would be more efficient than every laboratory attempting this (or not) independently
  - Present as guidelines rather than standards
  - Investigate and collaborate with other groups
  - Consider seeking input from organisations such as NICE to influence funding by Trusts
  - Post-analytical interpretation/advice may also be needed
  - Holistic approach would cover front end, analytical and post-analytical phases

Question 5 - How do we develop a series of audit tools to evaluate compliance with NSMs?

Comments from group 3:

- Auditing compliance with laboratory SOPs is essential, but who specifically benefits from auditing compliance with NSMs?
  - Standards Laboratory and working groups (nice to know work is useful!)
  - Health organisations (working to a national standard, same methods in different laboratories, comparable methods for surveillance)
  - Individual laboratory if NSMs closely followed
- Detailed audit for the benefit of others requires significant additional resources at local level
- Little incentive if not required for accreditation (a laboratory may use other recognised methods and already audit those)
- Noted that previous audits had poor response unless done by telephone with few general questions
- Detailed spreadsheet checklist could be useful if laboratories want to audit compliance, and data in a spreadsheet could be collected and analysed centrally if in standard format. These would need to be tailored for each method
- Reasons for non-compliances in audit may be very useful to indicate problem areas, availability of new methods etc
- Is there any evidence that non-compliance leads to poor performance in NEQAS (probably impossible to link as NEQAS is confidential)?
- Alternative/additional approach may be simple questions, suitable for telephone audit, e.g.
- Do you apply NSMs in full?
- Do you extract parts relevant to you from NSMs?
- Which parts do you not use and why?
- After a broad, brief telephone audit, it would then be easier to design a brief, written audit that focussed on problem areas highlighted by the telephone survey that took little time to complete
- Does audit of use have high priority for Evaluations and Standards Laboratory? Probably yes.
- Ask Regional microbiologists (RMs) to undertake this

Question 6 - How do we develop a network to re-establish a framework for conducting methodological evaluations to address key questions?

Comments from group 3:

- No discussion of this at meeting – a few suggestions
- No formal national framework for this ever existed
- Depends on interests of individuals
  - e.g. former PHLS Midlands group
- Bacteriology Evaluation Sub-group was previously set up
  - Role was to highlight evaluations needed, advise on study design, review proposals and assess results
  - No financial resources so little impact?
- Laboratories involved in evaluations will differ depending on the evaluation
  - Interested volunteers are preferable to reluctant conscripts
  - Beneficial to include non-HPA laboratories to ensure different hospital mix, ownership by all, not just HPA laboratories
- Full funding is required for evaluations. Possible sources?
  - HPA
  - DH
  - Commercial support
  - Research grants (not easy for technical evaluations)

Question 7 - How do we resource new activities?

Comments from group 3:

- Must recognise that the major investment is time and there are increasing demands on all staff
- May recoup time by reducing work on established NSMs, e.g.
  - Increase use of email in development of documents?
  - Assign individuals small groups to develop/update documents
  - Review documents less frequently e.g. 3 yearly (unless urgent)
  - Make review easier by marking changes on drafts for consultation and extending the listing of changes to documents in the re-issued methods
- Use of videoconferencing for some meetings
- Promote the case for increased central funding as an integral part of HPA activity (more wishful thinking?)

#### **2.2.4 Group 4 Virology Future**

Question 1 - What are the new demands and future priorities?

Comments from group 4:

- Requirement for molecular methods

- Clinical manuals for junior doctors to refer to for guidance
- Clinical guidance should be considered
- Interpretative guidance as important as SOPs
- Pre and post analytical reporting
- Set time lines for processing samples and identify which samples are appropriate
- Involve private laboratories in the process

Question 2 - Should we be developing 'front end' algorithms that advise on which investigations to do in certain clinical settings?

Comments from group 4:

- Yes and this is scheduled for discussion in Virology Working Group meeting in March

Question 3 - How should we move forward in the next 10 years to molecular methods?

Comments from group 4:

- Need to maintain the documents that we currently have
- Need feedback from the laboratories about what tests they see as rapid
- Move in to the following areas:
  - Molecular suites
  - Chip technology
  - Array technology
  - Near patient testing (use of tests in primary care)
- Understand implications of new technology such as automation on reorganisation of laboratories and sections within laboratories.
- Consider the implications of removing cell culture as a diagnostic test
- Involve health economists

Question 4 - How do we develop a network to re-establish a framework for conducting methodological evaluations to address key questions?

Comments from group 4:

- Look to CVN and RMs to re establish this
- Cross link with MiDAS
- Link in to national programmes

Question 5 - How do we develop a series of audit tools to evaluate compliance with NSMs?

Comments from group 4:

- Contact all laboratories and ask for an individual who can take responses and feed back to ESL. This must be done while asking them what they want from us and by outlining the CPD and CPA benefits of the process
- Might it be possible to link in to the results gained through clinical audits

- Carry out an audit of which documents each laboratory uses and what they require from the documents
- Link to commissioning process

Question 6 - How do we resource new activities?

Comments from group 4:

- NSMs are used by trusts to get funding from Primary care trusts
- Increase interactions with other working groups carrying out similar work to cut down on duplication of effort eg NICE.

## 2.3 Plenary

The day was concluded by Brian Duerden who highlighted the following points in response to the objectives of the meeting:

- It is not clear whether the NSMs recommend the best practice or minimum standards – which should it be and how do we decide?
- Standard Methods Working Groups should take the lead on development of the clinical guidance and clinical manuals for medical doctors and clinical scientists
- The profile of NSMs should be raised in the Healthcare Commission
- Guidance notes should be written on pre- (front end) and post analytical reporting
- Collaboration with other scientific and professional organisations such as NICE, British Heart Association, national programmes and DH should be considered
- Production of documents for specific patient groups should be considered

## Appendix 1

### List of Attendees

Name	Organisation
Baker Mark	Ashford
Barlow Katrina	ESL, CFI
Brian Duerden (chair)	DH
Bevan Valerie	ESL, CFI
Brown David	Health Protection Agency /UK CVN
Brown Derek	Cambridge
Bukari Sayed	Leicester
Collins Tim	Leeds
D'Arcy Stuart	NPHS Microbiology, Bangor
Evans Barry	CDSC, CFI
Farrington Mark	Cambridge
Fife Amanda	Kings College Hospital, H
George Rob	RSIL, CFI
Gillanders Sam	DH
Gray Jim	VRD, CFI
Gould Ian	Aberdeen
Harris Clare	Standards Unit, CFI
Ison Cathy	STBRL, CFI
James Peter	Welsh Microbiological Association
James Vivienne	QAL, Health Protection Agency
Logan Margaret	Gloucester
Marshall Roy	Southmead Hospital, Bristol
Martin Les	Preston
McClurg Barry	Belfast
McIntyre Paul	Dundee
Mutton Ken	Manchester
Pachenari Azra	Standards Unit, CFI
Patel Bharat	North Middx Hospital
Rasanayagam Priya	Institute of Biomedical Science
Shirley Jane	Birmingham
Stockley Jane	AMM
Siddiqui Ruhi	Standards Unit, CFI
Walton Christine	QAL, CFI
Watts Jacki	Bristol Royal Infirmary
Wilkinson Peter	CS, CFI
Wilson Shelley	St. Bartholomew's Hospital
Wood Bernard	CMMC University Hospitals NHS Trust
Wreghitt Tim	East of England, Regional Microbiologist

## **Appendix 2**

### **List of Questions**

#### **Questions for Groups 1 and 2**

- 1- Do NSMs continue to be fit for purpose?
- 2- What do NHS users of the NSMs want?
- 3- What can we stop doing?
- 4- What areas of the methods can we improve?
- 5- How can we encourage all laboratories to participate in the consultation process?

#### **Questions for Group 3 and 4**

- 1- What are the new demands and future priorities?
- 2- Should we be developing 'front end' algorithms that advise on which investigations to do in certain clinical settings?
- 3- How should we move forward to the next 10 years to molecular methods?
- 4- How do we develop a network to re-establish a framework for conducting methodological evaluations to address key questions?
- 5- How do we develop a series of audit tools to evaluate compliance with NSMs?
- 6- How do we resource new activities?