

# Quality in the Spotlight Conference



**Quality**  
2016

Elzenveld in Antwerp, Belgium 2016, 14<sup>th</sup> and 15<sup>th</sup> March

## Quality reflections in Laboratory Medicine

Secretary Mrs. Lia Konings and Chair Dr. Henk Goldschmidt, Foundation DCT, PO box 4201, 5004 JE Tilburg, The Netherlands.  
Tel. +31 85 401 8766 , Fax. +31 85 401 8764, E-mail: [TQMantwerp@gmail.com](mailto:TQMantwerp@gmail.com), Website: [www.qualityspotlight.com](http://www.qualityspotlight.com)

# **Quality in the Spotlight 14th and 15th March 2016**



**Quality**  
2016

The Antwerp conference 'quality in the spotlight' is a two-day conference on quality in medical laboratories. Over the years various quality related issues were addressed in a scientific setting where we learned from each other and from internationally well- known speakers. As a result, a rather boring subject was made pretty interesting!

While we placed quality in the spotlight, often laboratory medicine was actually in the spotlight because we took advantage of Jim Westgard's longitudinal rules (the Westgard rules) within and between laboratory controls. This needs more work!!





The coming conference is no different. We will continue to push the envelope! So join in, contribute and enjoy. We, together, have more work to do!

The Milan (IT) conference: "1st EFLM Strategic Conference 'Defining analytical performance goals - 15 years after the Stockholm Conference'" created some confusion. So, it is now time for the clean-up!



Cleaning up the mess: James Westgard (right) and Henk Goldschmidt at work!

To "clear the mess", different aspects of quality have to be combined in such a way so that the various parts work together. This means that the processes of manufacturing instruments and reagents, obtaining the sample, conducting the measurement, reporting, and interpreting the result for use in a clinical setting should all work together. This defines the loop. It also defines the quality 'fit for use.'

## Quality performance specifications

### Cleaning up our thoughts

Over a year ago (November 24th and 25th, 2014) the European Federation of Clinical Chemistry and Laboratory Medicine organized the first strategic conference in Milan (IT) to consider and discuss, from various perspectives, performance specifications of medical laboratory tests. The conference readdressed the "Consensus Agreement" from Stockholm. The papers from Milan's conference are published in Clin Chem Lab Med 2015; 53: 829-958.

However, some of the outcomes from this meeting have generated discussion in the scientific community. It has been argued that comments on the Stockholm conference made in Antwerp in 2004 (Accred Qual Assur 2004, 9:125 - 127), and the NEXUS concept outlined also in Antwerp in 2005 (Clin Chem Lab Med 2004, 42:868 - 873) have not been taken into account.

At this Antwerp meeting, we will continue to discuss the Stockholm and Milan outcomes using an open, independent, and out - of - the - box approach. As in the past we will publish a new set of consensus statements.

The layout of the second day of this conference is designed to reach an understanding of the meaning of quality characteristics in laboratory medicine. From the TE concept generating a total allowable laboratory error per test, we found a way to incorporate the concept of biological variation and create a NEXUS concept. So what will be next?

As with previous meetings, new ideas and questions will be posted. But, these need to be tested and evaluated. All this requires science and scientific debate. Join us in Antwerp for that debate.

## Sunday March 13th 2016

17.00 - 18.00	Registration desk open - welcome drink for all participants at the conference centre
20.00	Speakers dinner in town



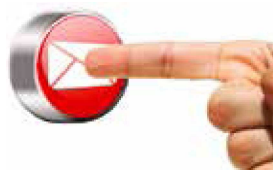
Day 1

Monday March 14th 2016

09.00 – 09.05

Welcome and opening conference

Pushing the envelope



09.05 - 10.15

Overview



09.05 – 09.40

**Callum Fraser**

Historical overview of setting analytical performance specifications (including the Stockholm consensus document and the Antwerp and EQALM comments on this) as a background for the 1th EFLM Strategic conference.



09.40 – 10.15

**Sverre Sandberg**

Analytical performance specifications: The consensus statement from the 1th EFLM Strategic conference. What are the main differences from the Stockholm consensus statement and how are the results from the Strategic conference taken forward. Is it possible to combine different models to obtain more pragmatic ways to set performance specifications?

10.15 – 10.45 Coffee break



**10.45 - 11.20**

**Rainer Haeckel**

Common concepts for establishing permissible uncertainty limits is to relate them on biological variation defining the rate of false positive results (model 1) or to base the limits on the state-of-the-art (model 2). The approach on biological variation should be preferred. Hitherto, recommendations were based on a linear relationship between biological and analytical variation leading to limits which are too stringent or too permissive. A working group of the DGKL proposes a combination of both models to overcome some disadvantages. The proposal is based on a non-linear relationship between biological and analytical variation leading to more realistic limits. The proposed algorithms can be applied to all measurands and considers any quantity to be assured.



**11.20 - 11.40**

**Sten Westgard**

**"Practical value of TAE in laboratory quality management"**

Historical review of quality control, quality assessment and quality management from Dr. Eugene K. Harris at the Aspen conference in 1976, through the Westgard rules into biology and beyond.



**11.40 - 12.00**

**Elvar Theodorsson**

**Total error versus measurement uncertainty: revolution or evolution?**

The error paradigm including total error and allowable total error struggles when representing numerous and complex factors influencing measurement results and commonly resorts to the simplest models of reality. The uncertainty paradigm suffers from complex mathematics and conceived impracticability in clinical chemistry.

The pros and cons of the total error and uncertainty paradigms need to be debated, making way for methods that can incorporate all relevant causes of uncertainty when making medical diagnoses and monitoring treatment effects. This development should preferably proceed as an evolution and not as a revolution.



**12.00 – 12.35**

**Mauro Panteghini**

**Allowable limits for measurement uncertainty across the traceability chain. Who is responsible for uncertainty at the different levels, industry, laboratories, users etc. ?**

An overview from the IFCC working group, The Milan Conference and the Paris meeting.

**12.35 - 14.00**

**Lunch break**



**14.00 – 14.30**

**David Armbruster**

Measurement Uncertainty (MU, m): Significance for the IVD Industry

After enactment of the In Vitro Diagnostics Directive (IVDD) in 2003, manufacturers have been adapting the principles of Metrology and in particular the concept of traceability. A formal traceability chain includes estimates of measurement uncertainty at every step. Identifying the sources of variability in the manufacturing process and quantitating them by estimating uncertainty allows manufacturers to minimize lot-to-lot variability for calibrators, controls, and reagents. However there are various options for calculating uncertainty and there is not yet an internationally accepted standard approach. Uncertainty is a useful concept for Industry because it allows manufacturers to better control and monitor the production of assay components. The manufacturer's responsibility ends with providing the uncertainty along with the target value of its products. Considerably more variability (uncertainty) is introduced when a manufacturer's assays are used in the "real world" of the clinical laboratory. The IVD Industry is challenged both with understanding how to account for uncertainty in the manufacturing process and how to explain uncertainty and its meaning to customers.



**14.30 – 15.00**

**Jim Westgard**

Resolving the battle between Total Analytic Error (TAE) and Measurement Uncertainty (MU). Comments and recommendations for establishing a comprehensive Quality Management System where accuracy is measured by TAE in the medical laboratory, traceability is measured by MU by manufacturers, and comparability is monitored by the Sigma quality achieved in PT/EQA programs.



**15.00 – 15.30**

**Jan Krouwer**

"TAE vs MU: What to do?"

Straightforward, out – of – the – box comments about the "total" in total error in medical laboratories from an industrial background including risk assessment strategies. Including comments on the paper "Proposal for the modification of the conventional model for establishing performance specifications" (CCLM 2015: 53 (6) 925 – 937). Total error, Stockholm and Antwerp statements, are also discussed.

**15.30 - 15.45**

**Tea break**



**15.45 – 15.55** Discussion and preliminary design of a set of consensus statements. Part 1.  
Is it possible to blend a hardcore industrial approach (ISO 9001, GUM) with biological and other (e.g., medical decision) quality characteristics into one model (ISO 15189). The lecture of David Burnett at the Antwerp meeting in 2007 was very helpful in that respect. But now we need a strict definition and proper formulas. An update and clearness is needed after Stockholm 1999, Antwerp 2004 and Milan 2014.

**15.55 – 16.00**      **Westgard award ceremony**



**16.00 – 16.35**      **Prof. Linda Thienpont**

This is the Westgard awardee lecture. It will deal with how traditional quality control in medical laboratories potentially can be improved. Two new tools for direct monitoring of patient medians and flagging rates will be presented. The first allows to assess the stability of laboratory/instrument performance on patient samples in comparison to the peer and the second translates the effect of instability on the flagging rate. Besides contributing to understanding of laboratory and test differences, the tools may also be able to demonstrate the validity of bias correction factors commonly used by individual laboratories or introduced on a national scale.

**16.35 - 16.45**    **Closing**

**17.00 - 17.45**    **Reception at the Antwerp townhall**

**18.30 -22.30**    **Dinner at the conference venue**

Admission to the dinner only by dinner ticket.

Dinner speech by Joris Delanghe

*"Antwerp: town on the crossroads of Europe or where cultures clashed in the past."*



**09.00 – 09.05****Opening conference: back to reality****POCT**

POCT really is taking off. In many physicians' offices, analytical instruments appear and the gamut of available tests enlarges. Not only are CRP, glucose and pregnancy tested for, but also HbA1c, HDL-cholesterol, BNP and HIV. Is the quality well defined; who is responsible for a correct analytical test result, the interpretation and archiving?

Technology is changing our world and also our perception and assessment of quality. For instance in the larger American institutions (e.g., St Louis Medical System), the control of the number and quality delivered by POCT glucose meters used throughout the hospital is totally lost. Yet, correct results for the 12% of critically ill patients is essential.

**09.05 – 09.35****Viviane van Hoof**

POCT, practical implications within and outside the hospital: guidelines from the Dutch and the Belgian working groups. (How) Can the quality of POCT results be guaranteed? Who is responsible? Does POCT work without medical lab involvement? POCT testing means convenience, but this is not always the best choice. Never underestimate the emotional impact of POCT on the physician, the physician's assistant as well as on the patient. Is there a definition for "proper lab test data"? What are we selling now and in the (near) future with POCT?

**09.35 – 10.05****Sharon Ehrmeyer**

POCT quality systems, such as CLIA and ISO 15189, have very different QC and QA guidelines. The U.S. bases the CLIA guidelines on test complexity.

- How would you rate a test as simple or as complex, waived or nonwaived?
- Which risks are involved when wrongly performed?
- Who is responsible, who can be prosecuted?

**10.05 - 10.35    Coffie break**

## Network laboratories

Network laboratories, with a high degree of specialization, become joint ventures between existing laboratories. Personalized medicine and DNA testing require specialization and enormous investment in equipment as well as personnel, making joint ventures within existing laboratory networks the only solution. While this is the technological forefront in our field, who is responsible and how is quality guaranteed?

**10.35 – 11.05**

**Marc Van Den Bulcke**

The Belgium Cancer Centre hosted by the Scientific Institute of Public Health coordinates the implementation of 'Next-Generation Sequencing' (NGS) testing into routine practice at the hospitals. NGS routine application will at first focus on tumor marker testing for clinical utility. This implementation will be organized through a pilot study wherein a number of new challenges for the laboratories will be addressed: cost-effective management through network organization, accreditation and external quality assessment for molecular NGS tests in (hemato) oncology, informed consent and privacy guarantee on genomic test data, training and education of personnel, data management and registration, reimbursement procedure. Each of these topics will be addressed and a status on the implementation will be presented.



**11.05 – 11.35**

**Joris Delanghe**

How much confidence should the requesting physician have in the laboratory system? Does it make sense to ask for quality control data next to the reported test results?



## Quality systems

Quality systems such as CLIA, ISO15189 and ISQua do not compensate for the lack of quality and competence of the individual health care worker (regardless of where located). On various levels in a health care organization, a lot of “rubbish” is communicated from employees (e.g., nurses) to customers (e.g., patients) and very often just to please the patient. From the employee’s point of view, the “very often” occurrence is not meant to be malicious. However, the consequences can be devastating for the patient. In addition to potential poor healthcare outcomes, a long lasting feeling of dissatisfaction often follows the interaction. How can we return to a traditional, individualized sense of quality that provides patient satisfaction?



11.35 – 12.05

**Stacy Walz**

Quality obtained in US laboratories is primarily defined by CLIA, while the FDA guards the quality of laboratory reagents. But who defines the quality of laboratory personnel, their performance, and the impact on the final quality of the test results?

12.05 – 12.35

**Christine Van Laer and Astrid Coppens**



Quality in Belgium laboratories. These laboratories are cost effective, friendly, customer directed and provide adequate consultation on various levels for colleagues, requesting physicians as well as patients. Being a part of the lab, are you willing to communicate with patients? And what are you willing to say; what kind of information will you provide, using which tools?

12.35 - 14.00    Lunch break

## New technologies



**14.00 – 14.30**

**Henk Goldschmidt**

Report from AACC 2015. Elizabeth Holmes created a paradigm shift in laboratory testing that is patient centered, cheaper, and delivers results faster. Is this really true? Like other innovations and promises, there are believers and non-believers. Chips are implemented to measure and influence certain body functionalities; the Nautilus project measures certain defined spots within the body. While continuous monitoring makes it possible to understand much more of the physical status of the patient, should these new approaches be cost-focused or just information focused on health and wellness?

## 14.30 – 15.15 Industrial snapshots

### 15.15 - 15.45 Tea break

## Practical Quality Management



**15.45 – 16.15**

**Marc Thelen**

The SKML is the Dutch organiser of external quality assessment schemes for all disciplines in laboratory medicine. The SKML feels a responsibility to do more than just compare laboratories. In case of differences between laboratories, SKML thinks that not the consensus or majority, but the truth should set the goal. Therefore SKML takes lead in the process of standardisation and harmonisation of laboratory results. The SKML is internationally well known and appreciated for its class A scheme for general clinical chemistry based on 24 commutable samples per year with value assignment in reference laboratories employing reference methods. By providing such a robust anchor for trueness verification to its participants, SKML reports are used by participants to correct for imperfections of the metrological traceability according to ISO17511 by IVD providers.

**16.15 – 16.30**

Discussion and preliminary design of a set of consensus statements. Part 2. Is it possible to blend a hardcore industrial approach (ISO 9001, GUM) with biological and other (e.g., medical decision) quality characteristics into one model (ISO 15189). The lecture of David Burnett at the Antwerp meeting in 2007 was very helpful in that respect. But now we need a strict definition and proper formulas. An update and clearness is needed after Stockholm 1999, Antwerp 2004 and Milan 2014.



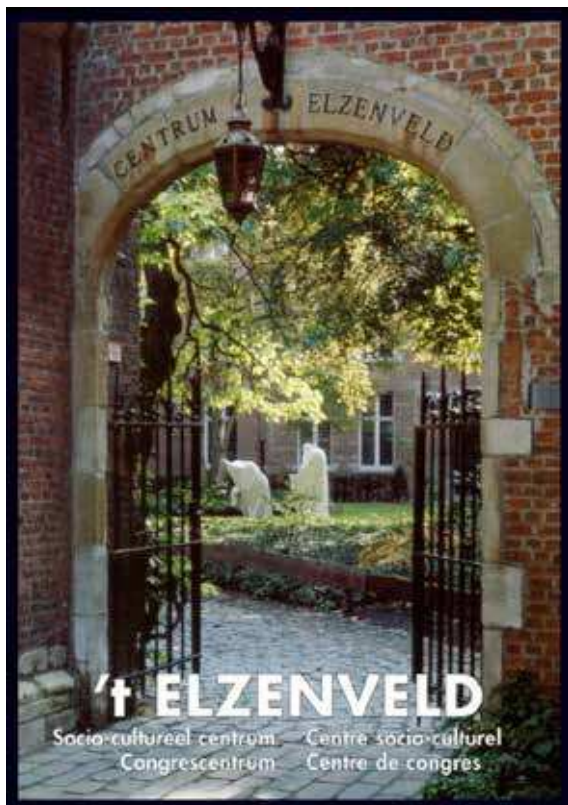
16.50 - 17.00 Closing remarks

17.00 - 17.30 Social gathering

## Antwerp 2016

Conference venue: 't Elzenveld situated at the Lange Gasthuisstraat 45 in Antwerp, Belgium.

The Elzenveld, dated XIIIth century, was the first “hospitale infirmorum” in Antwerp. The oldest still intact building is the nave of the chapel, erected around 1397 and extended with a spacious choir between 1443-1460. The Elzenveld is a socio-cultural center nowadays. The lectures are held in the Dr. L. Marquis auditorium. The poster session and industrial exhibitions will take place in the Kanunnik van Gessel hall.



### **Abstract Submission Form for Posters**

Fill in the form and save it as MS word document under "Name.poster.doc"

Send it to: TQMantwerp@gmail.com and vivienne@prikdienstnederland.nl confirming the reception will be sent to the e-mail address indicated in the form

E-mail address:

Title of the poster:

Name and Title of the Corresponding and presenting author

Additional Authors

Abstract: Maximum 200 words; use font Times New Roman 12

Posters will be on display during the entire conference, with appointed times for interaction with the authors.

Posters will cover a wide range of subjects including: software for QM, accreditation costs, laboratory-hospital interface, reference materials, error management, validation, and human resources management. A poster award will be presented at the Conference Dinner.

Submissions for the poster session will be reviewed by the program committee on the basis of a short abstract of not more than 200 words. As a guideline, the following questions should be answered:

- Describe the problem you have addressed.
- Why is this problem important?
- What is the original contribution of this work?
- Does it check and/or extend previously reported work?

Optional: if accepted, the author may choose to prepare a full paper on the topic for publication in the workshop proceedings.

## Proceedings

Proceedings were published in the "Journal of Accreditation and Quality Assurance", at least in part. The papers in JAQA give a fair impression of what the quality communion kept busy over the last decade. So far so good. What will happen with the papers during the next decade is unclear. The conference organization is still looking for a proper platform to publish.



## Practical information

### Conference Location

Antwerp lies at the heart of the European Union: It is a lively city whose international feeling and hospitable people enthusiastically welcome foreign guests.

The town first became a world commercial centre in the sixteenth century and was the cradle of commercial printing and Flemish art. It possesses a very large and vigorous harbor as well as being the diamond centre of the world.

The city is a mixture of many cultures. The citizens are called Sinjoors (Seigneurs) because of their elegance and enthusiasm for style and Burgundian way of life. This international awareness makes each person a citizen of the world and keenly supportive of commerce, industry, art and culture. The blinding success of Antwerp, designated the "cultural" capital of Europe in 1993, illuminated this yet again.



Antwerp, in the heart of Europe and Benelux and less than an hour away from the Community headquarters, is a city which is fully alive day and night. On the Schelde river, this metropolis welcomes merchants, businessmen, artists and travelers from all over the world. Spaniards, Jews, Greeks, Turks, Russians, Dutchmen, Germans, Chinese, Indians and Americans, to name but a few, are represented among the more than 135 nationalities which are at home in this world-class city. The various nationalities have their own clubs, centres, and religious institutions, which go towards making Antwerp into a cosmopolitan region.

**Conference address:** Conference Center "'t Elzenveld"  
Lange Gasthuisstraat 33-45  
B-2000 Antwerp  
Tel. +32-3-2027771  
Fax. +32-3-2027775

### Address for Conference information

Dr. H.M.J. Goldschmidt, Foundation DCT, P.O. box 4201, 5004 JE Tilburg,  
The Netherlands. Tel: +31 854018766, Fax: +31 854018764, E-mail: TQMantwerp@gmail.com  
Website: [www.QualitySpotlight.com](http://www.QualitySpotlight.com)

Secretary of the conference Mrs. Lia Konings , Tel: 0492-529416 E-mail: TQMantwerp@gmail.com

### **Registration desk**

The registration desk and conference secretariat are located in the Main Hall of the Congress Center.

The secretariat will be open:

Sunday March 13th, from 16.00 till 20.00

Monday March 14th, from 08.30 till 18.00

Tuesday March 15th, from 08.30 till 18.00

### **Venues**

The Scientific program, symposium lunch and coffee breaks, poster exhibition and commercial exhibition will all take place in the Congress Center, 't Elzenveld'

### **Registration fees**

Please use the attached registration form and return it as soon as possible to Dr. H.M.J. Goldschmidt or Vivienne van Benthem or Lia Konings, together with the full registration fee(s).

Your registration will then be confirmed. For payment instructions, please see below.

**Registration**    Before January 1st 2016: € 705  
                         After January 1st 2016: € 755

### **These fee cover:**

- participation in all scientific sessions
- symposium program
- abstract book
- lunches
- morning and afternoon refreshments
- welcome and farwell receptions at the Elzenveld

### **Payment instructions**

Participants are kindly requested to forward their registration fees, in Euro's, by bank transfer to the following bank account:

ABN-AMRO Bank, Heuvelring 88, 5038 CL Tilburg, The Netherlands

Account No: 63.08.57.385 IBA N: NL56ABNA 0630 8573 85 BIC code: ABNANL2A

Account holder: Foundation The Quality Meetings, Tilbutg, The Netherlands

Please indicate the names of the participants on all payment documents;  
or if known, the registration number.



Registration and receipt of fees will be acknowledged upon receiving payment. Please note that no registration will be finalized without proof of prepayment.

### **Use of credit card**

Payment can only be made by Visa credit card

Cancellation of registration

Registration fees less 50 euro for administrative costs, if written notice of cancellation is received before February 1st, 2016

No refunds will be made after this date.

### **Proceedings**

Extra copies of the proceedings can be ordered during the conference for € 75,-. This fee includes postage and handling.

### **Accommodation**

The following hotels have been suggested as the conference hotels:

Theater Hotel \*\*\*\*\*

Location: Arenbergstraat 30 (5 min\*)



Hotel Ibis Antwerpen Centrum \*\*\*

Location: Meistraat 39 (5 min\*)



\* walking distance to the Congress Center

In previous years we arranged a booking agency. But nowadays it is so easy to take care of this through the internet using various booking site, we would like to suggest to do so. Trivago.com, Booking.com and others facilitate such as well as the possibility to compare hotels and, in that way, fine-tune your booking.

If you need assistance, please contact Lia Konings or Vivienne van Benthem via [TQMantwerp@gmail.com](mailto:TQMantwerp@gmail.com) or [Vivienne@prikdienstnederland.nl](mailto:Vivienne@prikdienstnederland.nl) and we are pleased to help you out.

## **Access to Antwerp**

### **A. From Brussels airport (by train)**

There are train connections every 20 minutes from Brussels Airport to the Brussels North Station.

The journey to Antwerp Railway Station from Brussels North Station takes about 50 minutes.

Antwerp Railway Station is a 15-minute walk from the conference site. A taxi takes about 10 minutes.

There are city buses, but no subway in Antwerp.

### **B. By car**

Antwerp is easy to reach by car, following the E19 motorway from Brussels.

Car rental. Most major car rental companies have a desk at the Brussels Airport.

Parking facilities are available nearby the conference venue. Please note that you have to pay for your parking place.

### **C. By train from Brussels North Station**

There are several trains per hour from Brussels North Station to Antwerp. The fare for a single journey is approximately 8 Euro and the journey takes about 50 minutes.

## **Bank and Post office**

Banks are open from 9.00 - 16.00 hrs.

The main post office is open until 18.00 hrs.

## **Emergencies in Belgium**

The number for emergency calls is 112.

## **Insurance disclaimer**

While the Organizing Committee and Conference Secretariat have made every effort to ensure the safety and well-being of all conference members and their associates, responsibility cannot be taken for any accidents or damage that may occur during the symposium.

## **Speakers briefing**

Speakers should meet their session chairmen in the room of the presentation 20 minutes before the start of the session.

### **Social program**

On Sunday evening (17.00 – 18.00 hour) a Welcome Cocktail will be provided by the conference organization. The Conference Dinner is planned in the “kloosterzalen” of the Elzenveldcentre at Monday, March 14th.

The cost for the Conference Dinner is € 95 per person.

### **Students**

Limited funding for travel and attendance of the meeting may become available. Students (no others!) in need of financial assistance are requested to apply in writing through the Secretariat to the Chairman of the Organising Committee before January 1st, 2016. A copy of the studentcard should be enclosed.



### **General Information**

The meeting will be held in the Elzenveld in Antwerp (Belgium). The program consists of plenary sessions and poster presentations. The working language will be English, no simultaneous translation facilities will be provided.

### **Acknowledgements**

This symposium has been made possible, in part, by the financial support of the following companies sponsoring: Alere, DCT, pending.

## *How technology influences the quality management in laboratory medicine*

So we have some Gordian Knots to solve...

website: <http://www.QualitySpotlight.com>

Conference address:

Conference Center 't Elzenveld

Lange Gasthuisstraat 45,

B-2000 Antwerp, Belgium.



**So we have some Gordian Knots to solve...**

