CSA Group

Canadian Standards Association's New Standard for Pre-examination Processes

Anne-Marie Martel, M.T.

Chair of CSA Technical Subcommittee Z252.10 on Specimen Procurement

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Z316.7 New Standard for Pre-Examination Processes

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Anne-Marie Martel, Medical Technologist

- Chair of CSA TSC Z252.10
- Member of CSA TCZ252, Medical Laboratory Quality Systems
- Scientific Coordinator at OPTMQ (Ordre professionnel des technologistes médicaux du Québec)

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Outline of the presentation:

- CSA committees
- History
- Target audience
- Development process and timeline
- Importance of pre-examination processes
- Scope and terminology
- Content
- Next steps

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CSA TSC Z252.10

- Anne-Marie Martel, M.T., Chair
- Michael Noble, MDFRCPC, Vice-Chair
- Sheila Woodcock, ART, MBA, FCSMLS(D), Vice-Chair
- Robert Rennie, PhD, FCCM, D(ABMM), Member
- And many others...

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Z316.7 *Primary sample collection facilities and medical laboratories – Requirements for requesting, collecting, transporting, and storing samples for patient safety and quality of care.*

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History:

White paper published in Canadian Journal of Medical Laboratory Science[1]:

[1] *Is there a role for Medical Laboratory Science in Patient Safety in Canada?*

Davis, Kurt H., CJMLS, Vol. 70, No3, June 2008.

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Highlights:

- Absence, in many provinces, of regulatory control of specimen procurement;
- Can be delegated in some provinces;
- Lack of standardisation in training and education programs;
- Limited accessibility of standards in Canada for specimen procurement;
- Lack of regulatory bodies for medical technologists and medical laboratory assistants in some provinces.

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Documents used in the standard development:

- OPTMQ Rules of practice (source documents)
- ISO 15189:2007
- CLSI Standards and Guidelines
- Health Canada Infection Control Guidelines
- Etc.

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Target audience:

Facilities performing pre-examination activities:

- Medical laboratories;
- Hospitals and associated collection centers;
- Bedside collections;
- Private and public collection service organizations;
- Doctor's offices;
- Home collections.

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Application and implication of the standard:

- Standalone or in conjunction with ISO15189;
- Adoption by accreditation bodies;
- Adoption by health ministries;

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Development process and timeline:

- October 2008: Presentation of CSMLS white paper
- October 2009: Presentation of draft to TCZ252
- April 2010: Business plan / proposal for new work item and identification of stakeholders
- October 2010: Approval of title and scope by TCZ252 and appointment of Chair for TSC.

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Development process and timeline:

- December 2010: Call for participants to form the new TSC Z252.10 on Specimen Procurement
- February to November 2011: TSC draft standard development
- December 22, 2011 to February 20, 2012: Public review
- February 2012 to April 2012: Review of comments received

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Development process and timeline:

- Review by CSA's editorial staff
- Submission of final draft standard to TC for approval
- Publication of the standard
- Maintenance of the standard

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Importance of pre-examination processes

- Up to 85% of medical decisions are based on results from the medical laboratory[2];
- Physical safety of the patient;
- The majority of errors occur in the pre-examination phase.

[2] Foubister, V,: Bench press: The technologist/technician shortfall is putting the squeeze on laboratories nationwide, *CAP Today*, September 2000.

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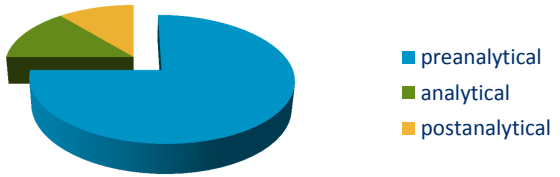
- Errors in Laboratory Medicine:
  - Preanalytical: 31.6% to 75%
  - Analytical: 13.3% to 31.6%
  - Postanalytical: 9% to 31.6%



Bonini P, Plebani M. Ceriotti F. Errors in laboratory medicine. *Clin Chem* 2002; 48:691-8.

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- Preanalytical variability: the dark side of the moon in laboratory testing:
  - *"Lack of standardized procedures for sample collection, including patient preparation, specimen acquisition, handling and storage, account for up to 93% of the errors currently encountered within the entire diagnostic process."*

Lippi G, Guidi GC, Mattiuzzi C, Plebani M. Preanalytical variability: the dark side of the moon in laboratory testing., *Clin Chem Lab Med*. 2006;44(4):358-65.

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Scope of the standard:

- To establish quality requirements for:
  - Sample requests
  - Collection
  - Transport, and
  - Storage

  To ensure patient safety and quality of care are at the forefront of the pre-examination process.
- Beyond the scope:
  - Specific procedures
  - POCT (covered in CAN/CSA-Z22870)

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Terminology used in the standard:

- Pre-examination activities: *steps starting with the sample request, followed by the preparation of the patient, collection of the primary sample, transport of the sample to and within a laboratory, accessioning of the sample, stabilization of the sample and storage of the sample, and ending when the examination activities begins.*

"preanalytical phase"

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Terminology used in the standard:

- Primary sample or specimen: *the sample collected from or by a patient, which is still in its original collection container, and is to be used for examination purposes.*
- Sample or aliquot: *a portion removed from the primary sample that is used for examination purposes.*

Note: the term sample was also used to include both the primary sample and sample in situations such as handling, transport and storage.

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Contents:

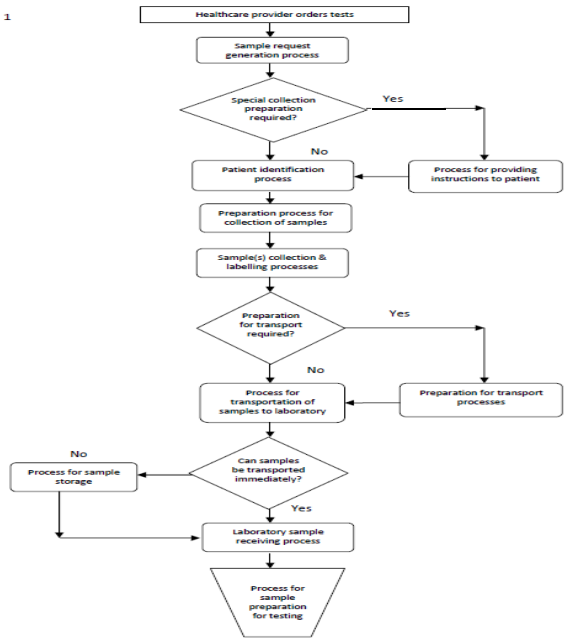
1-Scope

2-Reference publications

3-Definitions

4-Pre-examination processes

Figure 1



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Contents:

1-Scope

2-Reference publications

3-Definitions

4-Pre-examination processes

5-Quality management system

6-Patient safety and quality of care

7-Accomodation and environmental conditions

8-Equipment and supplies

9-Personnel

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Contents:

10- Infection prevention and control:

- Patient waiting areas
- Hand hygiene
- Personal protective equipment
- Single use and reusable equipment
- Cleaning of sample collection environment
- Collecting from patients requiring additional precaution

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Contents:

10- Infection prevention and control

11- Primary sample collection

- Instructions
- Sample requests
- Verification of the patient's identification
- Verification of sample request form
- Patient consent
- Pre-examination requirements
- Phlebotomy procedures
- Special requirements for samples by discipline

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Contents:

10- Infection prevention and control

11- Primary sample collection

12- Identification of samples

13- Sample integrity

14- Sample receipt, assessment, processing and storage

15- Transport of samples

Including:

- Automated (pneumatic tube) delivery system
- Home collections

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Informative annexes:

A: Quality management requirements: adapted from section 4 of ISO15189:2007.

B: Maximum blood draw volume table

C: Biochemistry samples

D: Hematology samples

E: Coagulation samples

F: Transfusion medicine samples

G: Pathology samples

H: Cytology samples

I: Immunohistochemistry samples

J: Microbiology samples

K: Molecular diagnostics samples

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Next steps:

- Publication of standard
- Translation to French
- Submission to Standards Council of Canada
- Submission to ISO TC212

Thank you!

Questions or comments?