A New Canadian Standard for Sample Collection and Handling to Improve Patient Safety and Quality of Care

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Global Standardization of the Preanalytic Process of Laboratory Testing

JCCLS Symposium

April 4, 2013

Outline of the presentation:

- Global standardization
- Patient safety
- About CSA
- Importance of pre-examination processes
- The new Canadian standard
  - Target audience
  - Scope and terminology
  - Content
  - Next steps

Global Standardization

The *dynamic force in current* globalization - the thing that gives it its unique character - is the *new found power for individuals to collaborate* and compete globally.

Thomas L. Friedman
NY Times journalist
Author of "The World is Flat"

WHO World Alliance for Patient Safety 2004

Surgical Safety Checklist

World Health Organization | Patient Safety
A World Alliance for Safer Health Care

Before induction of anaesthesia

(with at least nurse and anaesthetist)

Has the patient confirmed his/her identity, site, procedure, and consent?
- ☐ Yes

Is the site marked?
- ☐ Yes
- ☐ Not applicable

Is the anaesthesia machine and medication check complete?
- ☐ Yes

Is the pulse oximeter on the patient and functioning?
- ☐ Yes

Does the patient have a:

Known allergy?
- ☐ No
- ☐ Yes

Difficult airway or aspiration risk?
- ☐ No
- ☐ Yes, and equipment/assistance available

Risk of >500ml blood loss (7ml/kg in children)?
- ☐ No
- ☐ Yes, and two IVs/central access and fluids planned

Before skin incision

(with nurse, anaesthetist and surgeon)

- ☐ **Confirm all team members have introduced themselves by name and role.**
- ☐ **Confirm the patient's name, procedure, and where the incision will be made.**

Has antibiotic prophylaxis been given within the last 60 minutes?
- ☐ Yes
- ☐ Not applicable

Anticipated Critical Events

To Surgeon:
- ☐ What are the critical or non-routine steps?
- ☐ How long will the case take?
- ☐ What is the anticipated blood loss?

To Anaesthetist:
- ☐ Are there any patient-specific concerns?

To Nursing Team:
- ☐ Has sterility (including indicator results) been confirmed?
- ☐ Are there equipment issues or any concerns?

Is essential imaging displayed?
- ☐ Yes
- ☐ Not applicable

Before patient leaves operating room

(with nurse, anaesthetist and surgeon)

Nurse Verbally Confirms:
- ☐ The name of the procedure
- ☐ Completion of instrument, sponge and needle counts
- ☐ Specimen labelling (read specimen labels aloud, including patient name)
- ☐ Whether there are any equipment problems to be addressed

To Surgeon, Anaesthetist and Nurse:
- ☐ What are the key concerns for recovery and management of this patient?

This checklist is not intended to be comprehensive. Additions and modifications to fit local practice are encouraged.

Revised 1/2009

From Joint Commission U.S.A.

2013 Laboratory National Patient Safety Goals

The purpose of the National Patient Safety Goals is to improve patient safety. The goals focus on problems in health care safety and how to solve them.

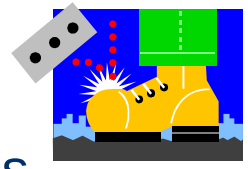
Identify patients correctly	
NPSG.01.01.01	Use at least two ways to identify patients. For example, use the patient's name *and* date of birth. This is done to make sure that each patient gets the correct medicine and treatment.
Improve staff communication	
NPSG.02.03.01	Get important test results to the right staff person on time.
Prevent infection	
NPSG.07.01.01	Use the hand cleaning guidelines from the Centers for Disease Control and Prevention or the World Health Organization. Set goals for improving hand cleaning. Use the goals to improve hand cleaning.

Canadian Standards Association History

- Founded in 1919 as the Canadian Engineering Standards Association (CESA)
- Federally chartered to create standards
- The first standards issued by CESA were for steel railway bridges, in 1920
- In 1927 CESA published the Canadian Electrical Code
- 1940 CESA assumed responsibility for testing and certifying electrical products intended for sale and installation in Canada.

Canadian Standards Association History …
continued

- 1944 renamed Canadian Standards Association
- 1946 introduced the certification mark now widely recognized
- In the 1960s, CSA developed national Occupational Health and Safety Standards, creating standards for headgear and safety shoes
- 1970s, the CSA began to expand its involvement in consumer standards, including bicycles, credit cards, and child resistant packaging for drugs.



CSA Today

- Not-for-profit membership-based association serving business, industry, government, and consumers in Canada and the global marketplace
- Re-branded in 2012 with three major sectors:
  - the Canadian Standards Association - for standards development, information products, sale of publications, training, and membership services
  - CSA International - for product testing and certification
  - OnSpeX- for consumer product evaluation based in Cleveland, Ohio
- 57 areas of specialization
  - climate change
  - business management
  - safety and performance standards, including those for electrical and electronic equipment, industrial equipment and construction materials
  - health care
- 7,500 members involved in standards development
- Accredited by Standards Council of Canada

CSA Health Care Program

- 220 standards in 15 subject areas
- Improving patient safety (i.e., reducing adverse events or critical incidents)
- Increasing the safety of health care workers (i.e., reducing workplace accidents and infections)
- Ensuring the electrical safety of medical devices
- Promoting the safe design, construction, and management of health care facilities and their subsystems; and
- Establishing secure, reliable health information systems.
- In addition a number of guidance and support documents have also been published.

Examples of High‐profile CSA Health Care Standards

- **Z902, Blood and blood components** (management system standard to enhance the quality and safety of blood collection and transfusion)
- **Z900 series, Cells, tissues, and organs for transplantation and assisted reproduction** (management system standards to improve the safer handling of human cells, tissues, and organs for human transplant).
- These standards are referenced in safety regulations under Health Canada's Food and Drugs Act which came into force on December 7, 2007.

CSA Technical Committee Z252
Medical Laboratory Quality Systems

- Established in 1988 under the authority of the Strategic Steering Committee on Health Care
- Balanced matrix membership:
  - producer interest,
  - user interest,
  - regulatory interest, and
  - general interest
- Serves as the Canadian Mirror Committee to ISO/TC 212 *Clinical Laboratory Testing and In Vitro Diagnostic Test Systems*, ensuring active Canadian delegate participation at ISO/TC 212 meetings.

Current TC Z252 Activities

- Participation in *ISO/TC 212 Clinical laboratory testing and in vitro diagnostic test systems*
  - WG1, Quality and competence in the medical laboratory
  - WG2, Reference systems
  - WG3, In vitro diagnostic products
  - WG4, Antimicrobial susceptibility testing
- Periodic review of existing standards portfolio documents
- Contribution to Infoway work on standardization of nomenclature
- Communication and cooperation with other national organizations: Health Canada, Accreditation Canada, CAP-ACP, CSCC, CSMLS, etc.
- Identification of need for new national standards or guidelines.
  - Evaluation of laboratory developed methods
  - Antimicrobial susceptibility testing

Z316.7 New Standard for Pre-Examination Processes

Z316.7 - 12

Primary sample collection facilities and medical laboratories – Patient safety and quality of care - Requirements for collecting, transporting, and storing samples

Technical Sub-Committee

CSA TSC Z252.10

- Anne-Marie Martel, M.T., Chair
- Michael Noble, MD,FRCPC, Vice-Chair
- Sheila Woodcock, ART, MBA, FCSMLS(D), Vice-Chair
- Representatives of the medical laboratory community from across Canada

Z316.7 New Standard for Pre-Examination Processes

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.

Z316.7 New Standard for Pre-Examination Processes

Rationale:

- Lack of standardisation in training and education programs;
- Limited availability of guidance documents in Canada for specimen procurement;
- Absence, in many provinces, of regulatory control of specimen procurement;
- Lack of regulatory bodies for medical technologists and medical laboratory assistants in some provinces.

Z316.7 New Standard for Pre-Examination Processes

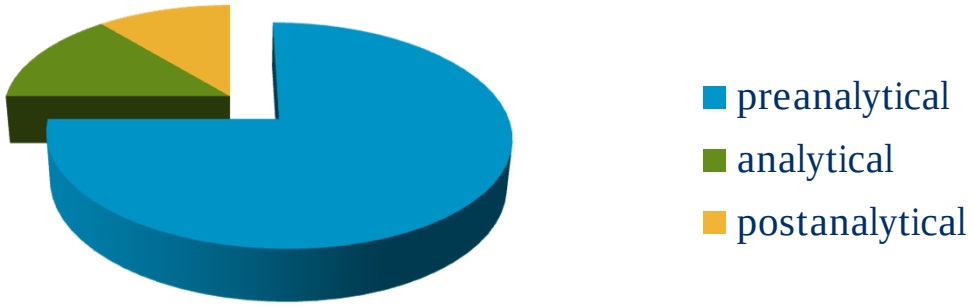
Importance of pre-examination processes

- 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.

Z316.7 New Standard for Pre-Examination Processes

- Errors in Laboratory Medicine:
  - Pre-analytical: 31.6% to 75%
  - Analytical: 13.3% to 31.6%
  - Post-analytical: 9% to 31.6%



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

Z316.7 New Standard for Pre-Examination Processes

- Pre-analytical 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.

Z316.7 New Standard for Pre-Examination Processes

Target audience:

Facilities performing pre-examination activities:

- Medical laboratories;
- Hospitals and associated collection centres;
- Nursing Homes and other special care facilities;
- Private and public collection service organizations;
- Doctor’s offices;
- Home collections.

Z316.7 New Standard for Pre-Examination Processes

Documents used in the standard development:

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

Z316.7 New Standard for Pre-Examination Processes

Application of the standard:

- Stand alone or in conjunction with ISO15189
- Adoption by accreditation bodies
- Adoption by health ministries

Z316.7 New Standard for Pre-Examination Processes

Scope of the standard:

- To establish quality requirements for:
  - 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)

Z316.7 New Standard for Pre-Examination Processes

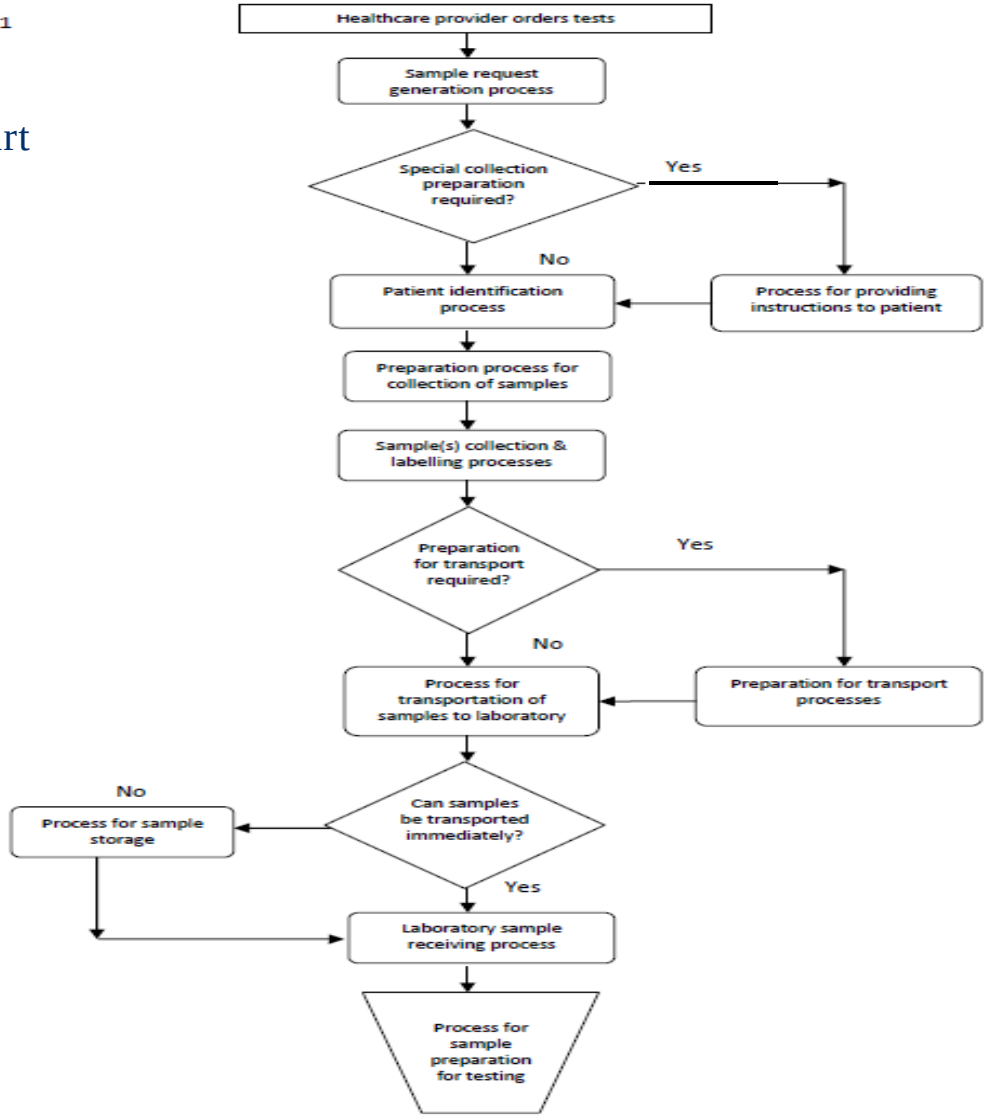
Terminology used in the standard:

- 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.*

  “pre-analytical phase”

Figure 1

Pre-examination Processes flowchart



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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.

Z316.7 New Standard for Pre-Examination Processes

Contents:

1-Scope

2-Reference publications

3-Definitions

4-Pre-examination processes

5-Quality management system

- ISO 15189-07 (Annex A)
- ISO 9001
- CLSI GP26-A4

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6-Patient safety and quality of care

- Patient communication
- Ethics
- Privacy
- Confidentiality
- Patient physical safety
- Prevention of errors and nonconformities

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7-Facility conditions

- Space allocation and design
- Patient and personnel comfort and safety
- Controlled access
- Housekeeping

8-External services, supplies, and equipment

- Expiry dates
- Reusable vs sterile supplies
- Personal protective equipment (PPE)

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9-Personnel

- Training
- Records
- Competence assessments

10- Infection prevention and control:

- Patient waiting areas
- Hand hygiene
- Collecting from patients requiring additional precautions

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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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12- Identification of samples

13- Sample integrity

- Criteria for sample rejection
- Phlebotomy procedures

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: Biochemistry samples

C: Hematology samples

D: Coagulation samples

E: Transfusion medicine samples

F: Pathology samples

G: Cytology samples

H: Immunohistochemistry samples

I: Microbiology samples

J: Molecular diagnostics samples

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Informative Annex C for Biochemistry Samples

- Blood samples:
  - Collection
  - Preservation and storage
- Urine samples
- Other samples

Informative Annex K for Molecular Diagnostics Samples

- Collection, handling and storage
- Blood and bone marrow samples
- Other types of samples
- Handling and storage of extracted DNA and RNA

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Next steps:

- Promotion and marketing of standard
- Translation to French
- Proposal to develop supplementary product to provide templates for key documents.
- Submission to Standards Council of Canada
- Use as the basis for new Technical Report developed by ISO TC212 WG1

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Thank you!

Questions or comments?