

10 years of experience and observation, so what?

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Chairing the sterilisation community for 10 years

- Amazing journey
- Meeting thousands of people
- Attending congresses, workshops
- Visiting CSSD
- Helping countries starting an association and defining their roadmap



What did i see?

Limits difficult to overcome

enthusiasm
motivation
commitment

learning

new
national
associations

sharing
networking
collaboration with
industry

improvement

education
programs

science

guidelines



Limits?

- Weight of habits is considerable:
 - **practices**
 - **management methods still copied from care services, with nursing staff as managers and operators**
 - **lack of independence (under the responsibility of OT, infection control...)**
 - **long way from a quality approach**
- High resistance to change
- Lack of awareness of the importance of implementing good practices
 - **professionnals themselves**
- Managers' profiles not adapted to the evolution of CSSDs
 - **CSSD is a production department, not a care unit**
- Lack of awareness of the importance of CSSDs:
 - **national health authorities,**
 - **hospitals directors**



Overcome the limits

- If nothing moves on the part of the authorities or hospital management, **it's up to us to drive change.**
- To achieve it, it requires:
 - a real management of CSSDs
 - professionals with leadership skills and scientific knowledge on production processes, traceability...
- Accepting change, supporting change and driving change
- If the professionals in place don't see themselves in this development, other profiles can do it.



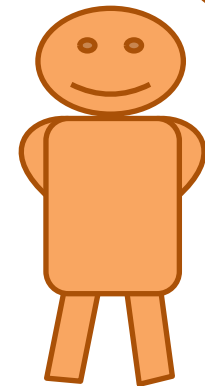
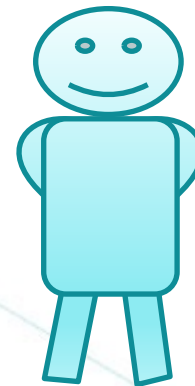
At a country level



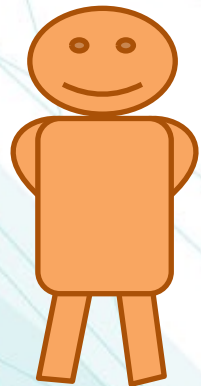
some countries
have found the
levers for
change



some countries
remain stuck
and are not
moving forward



Motivation

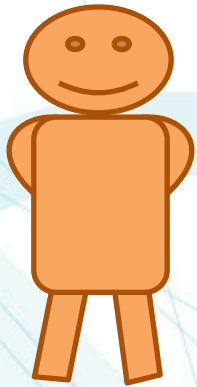


No motivation



It is health of
people at
stake!





No
education

No
recognition

No
money

No local
guidelines

No local
regulation

learn on
internet, teach
the operators

it comes with
expertise and
professionalism

a lot can be
done without
money

see
WFHSS
guidelines

act as if



- The speech today is about YOU
- What can YOU change at YOUR level
 - Without money
 - Without national regulation

But with a good dose of motivation and a good sense of management & leadership!



Some real-life situations...

- A few examples that illustrate the global recurrence of problems , nonetheless simple to resolve.
- Anecdotes taken from different places & countries
- What is wrong?
- What could be done?



Choice to focus on

- Cleaning
- Packaging



Cleaning area: case 1



WD are empty and
operators clean manually in
basins (« quicker »)
No rinsing.



Cleaning area: case 2

« Operator alone in the cleaning area,
a few sets of cleaned instruments are in the pass
through,

the WD are empty,

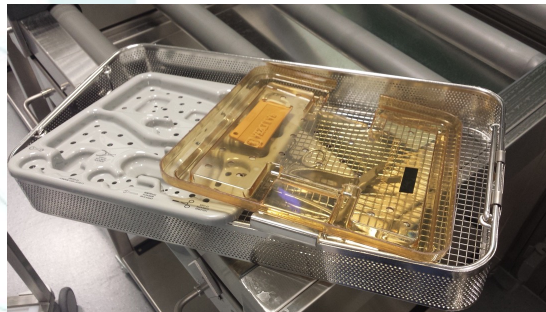
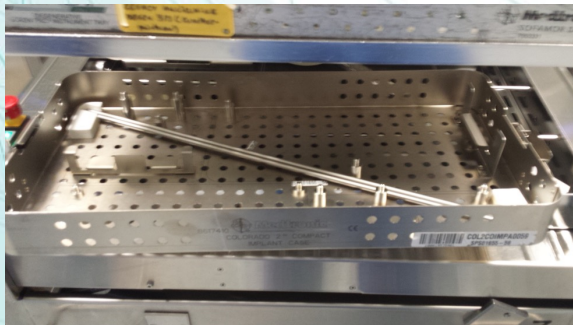
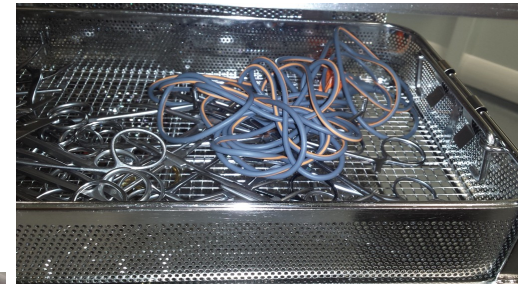
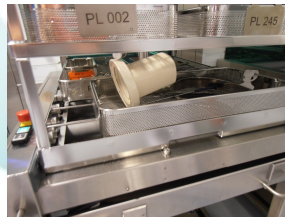
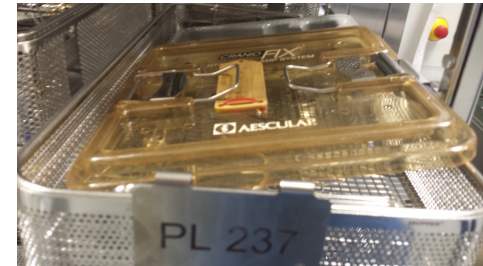
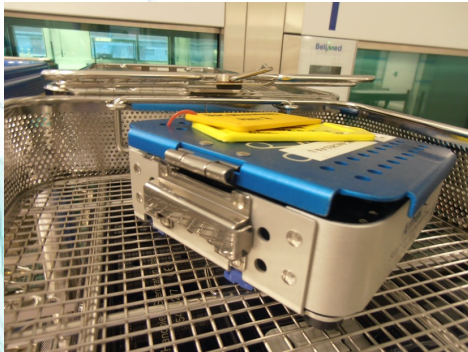
The sets could have been obviously cleaned in the
WD »

Response of the manager : « oh this operator arrived
one week ago, he does not know ».



Cleaning area: case 3

Loading of WD:



What is wrong?

- The importance of cleaning in the process is underestimated
- The danger of manual cleaning is not identified as such.
- The part of manual cleaning is much higher than it should be.
- The good practices for WD loading are not clear.
- WD are underused or misused
- Education of operators is not managed
- Education of managers is perfectible



Automated cleaning/manual cleaning

- Is a big issue, seen everywhere
- Automated cleaning and manual cleaning **are not equivalent**
- It should not occur anymore
- Manual cleaning is only when IFUs recommend it and not the choice of the operator
- Manual cleaning is operator dependant, not controlled , not reproducible, not validable..



What shall be done?

« *Only clean items are sterilised properly* »

is not just a sentence

it's a principle that every CSSD manager should apply.

- Education of CSSDs managers is key:
 - STOP consider cleaning is a innate science
 - STOP thinking that cleaning RMDs is like washing dishes at home
 - STOP having less trained operators in cleaning area,
 - STOP posting new recruits in cleaning area, it is the most challenging of all steps

↳ **cleaning is for experienced operators**
- Operators are multiskilled and able to work at each workstation in the CSSD to have a whole understanding of the work
- Working instructions and procedures are available to ensure that everyone works in the same way.



What shall be done?

« *Only clean items are sterilised properly* »

is not just a sentence

it's a principle that every CSSD manager should apply.

- **All** RMD must be cleaned in a WD with a proper program (exception : see IFUs)
 - **consistently: whoever, whenever, emergency or not**
 - **It is not the choice of the operator**
- Loading of the WD is essential, even if precleaning has been performed
- Controls must be implemented at unloading and recorded



Packaging: case 1



Packaging: case 1

- This container is ready to be used the technician is going to put the tray full of instruments in it.
- Will this container keep sterility until the use?
- NO : neither this time or the next.



What is wrong?

- importance of packaging in the process is underestimated
- container should be put aside and sent for repair immediately
- operator should know it
- education of operators is not managed
- a proper management of containers is not in place



Packaging : case 2

- Textiles (linen) still largely used despite all the warnings:
 - They are not SBS (no microbial barrier)
 - Short expiry dates (1 week or 2), not sustainable



It is the role of the CSSD manager :

- To warn OT, infection control and propose a proper solution for packaging
- To conduct studies to compare costs and pro/cons



Packaging : case 3

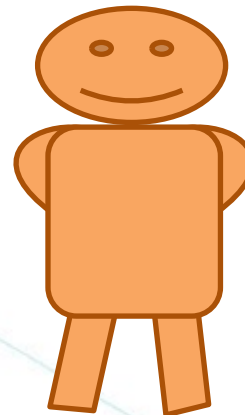
Containers in the sterile area ready to go

Bad shape, distorted....

No tamper evidence locks



No tamper
evidence
locks?



It is not
written in the
national
guidelines!

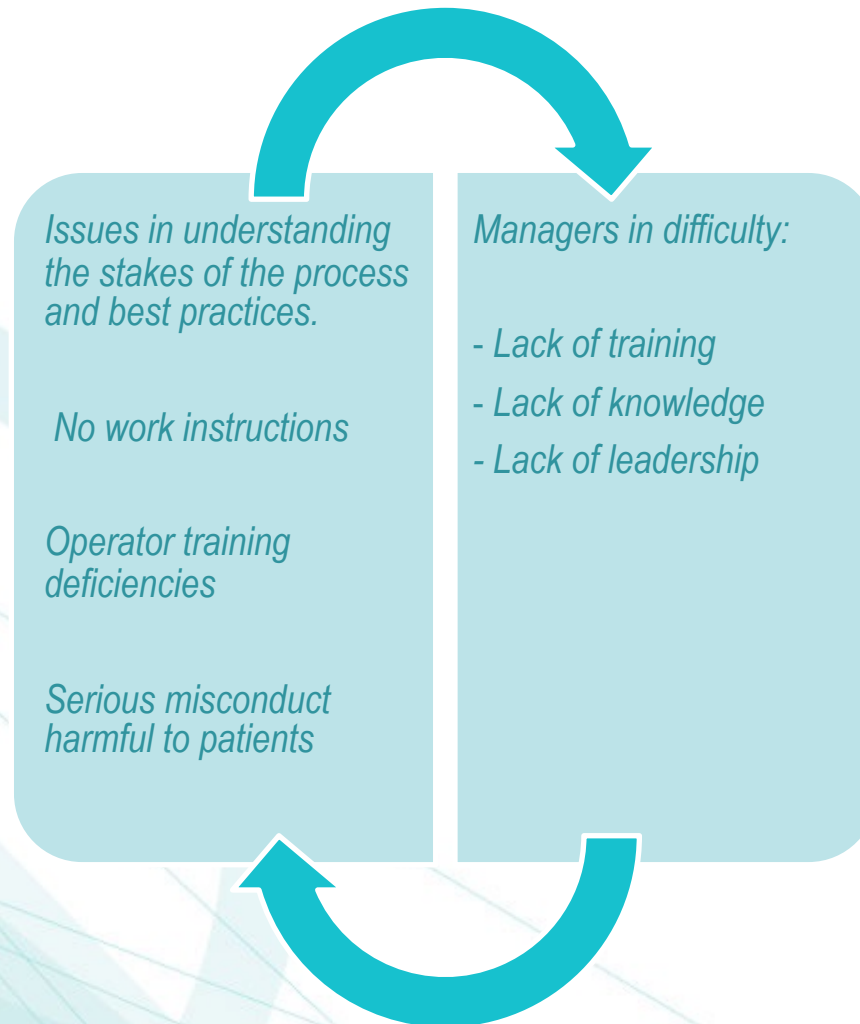


What could be done?

- Understand that packaging is key to maintaining sterility up to the point of use.
- STOP textiles
- Use containers only if controls, repairs and maintenance are effective
- Educate operators
- Write working instructions



To summarize



Let's remain optimistic and positive

When there's a problem there's a solution



Which perspective do you prefer?

Eagle eye view?



Mouse eye view?



Get some height



What is seen from above?

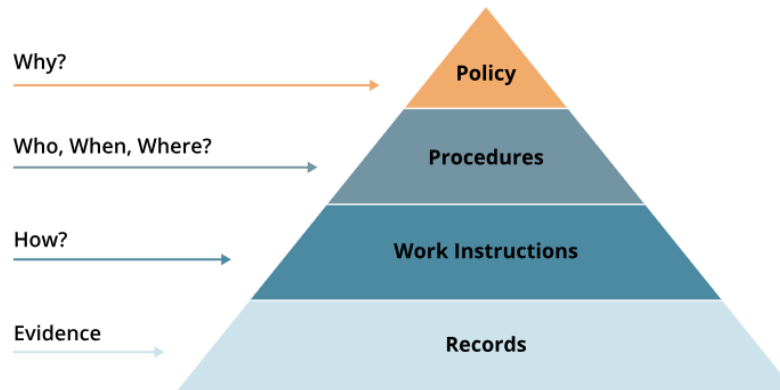
- Like a map



- Mapping is precisely the key element of a QMS
- Would the solution lie in a QMS?



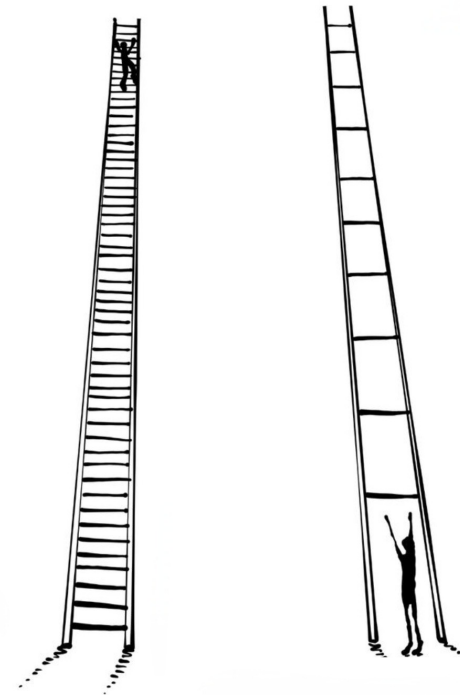
The
solution lies
here



Implementing a QMS

- Often seen as too complex or boring
- Can be long
- Help from quality engineers
- Set realistic targets
- Small steps but at a good pace

Rome wasn't built in 1 day...



What would be the top priorities?

QMS a minima

- HR Organisation chart & Job descriptions
- Working instructions & *procedures*
- Records

Starting with a risk analysis to classify tasks and enable a relevant prioritisation



In-house training program

- for both new and existing staff
- reference = working instructions
- Objectives:
 - All operators are able to work at each workstation (clean, pack, assemble, sterilise...)
 - All operators are qualified



HR Organisation chart & Job descriptions

HR organisation chart

- **illustrates the different positions and the hierarchy between employees.** T
- helps to visualise who is responsible for which functions
- how the different positions interact with each other.

Job description

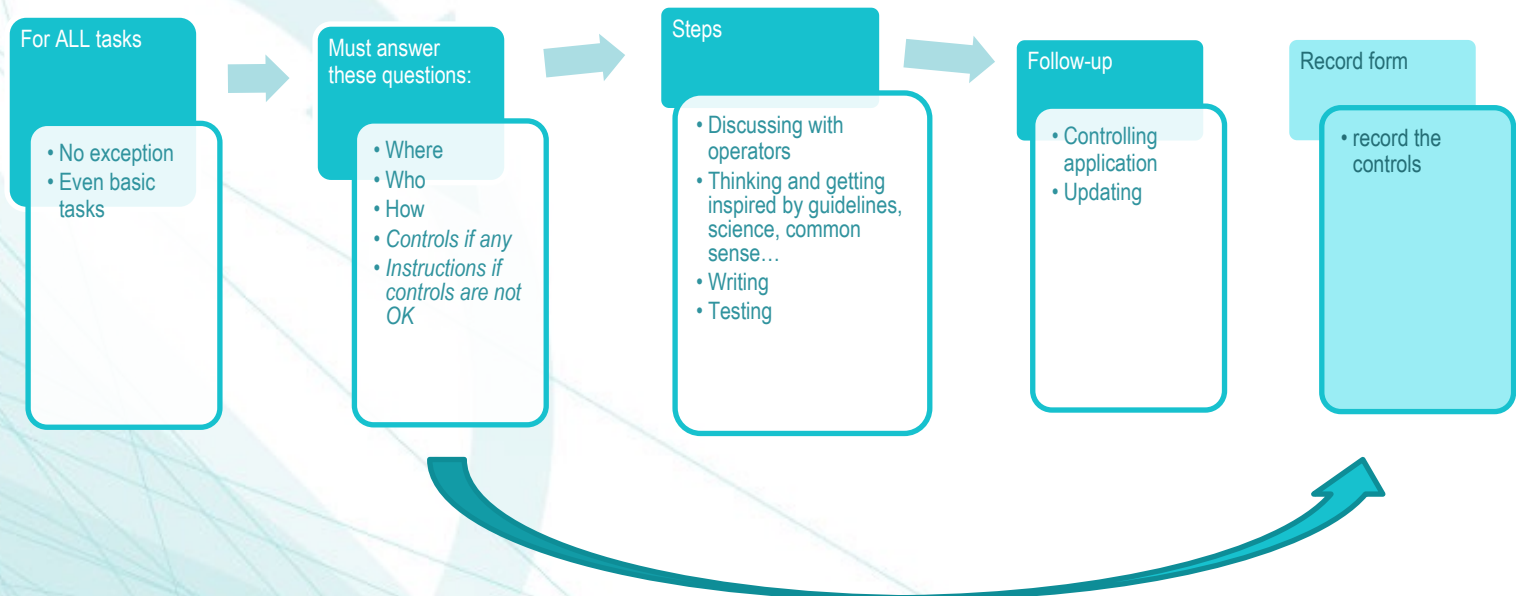
- Responsibilities and tasks to be performed.
- Education, qualifications required (country dependent)
- Skills and aptitude.
- Functional relationship.
- Physical, chemical and infection risks.



Working instructions (WI)

Write WI is not just write down what is currently done.

Each WI is an opportunity to ask the right questions: why, who, where, how.



Risk analysis with a matrix

Impact:
how severe would the outcomes be if the risk occurs?

Probability:
what is the probability the risk happens?

	1 insignificant	2 minor	3 significant	4 major	5 severe
5 almost certain	Medium 5	High 10	Very high 15	Extreme 20	Extreme 25
4 likely	Medium 4	Medium 8	High 12	Very high 16	Extreme 20
3 moderate	Low 3	Medium 6	Medium 9	High 12	Very high 15
2 unlikely	Very low 2	Low 4	Medium 6	Medium 8	High 10
1 rare	Very low 1	Very low 2	Low 3	Medium 4	Medium 5



Implementation of a in-house training program

- Mentorship is the good option
- Reliability of mentors has to be verified first
- Training sequence:
 - Packing
 - Assembly (regular sets, implants, endoscopy, motors...)
 - Sterilisation
 - Cleaning
 - Unloading WD



In practice



The new operator is always with a mentor, under his/her responsibility.
The mentor explains the tasks showing the WI or other quality documents
They work together until the training is completed

- When training for a step is completed the new operator informs the CSSD manager that he/she is ready to be evaluated.
- The CSSD manager evaluates with a grid, watching and questioning
- If OK the new operator is declared qualified for the step and can go on .
- Once qualified for a step he/she can work alone.

**Qualification of the mentors:*

- Start with experienced staff
- Assesment by CSSD manager
- Qualification



Example: grid for packaging

Name of operator /date/Name of assessor/signatures Qualified: yes <input type="checkbox"/> no <input type="checkbox"/>			
Packaging	Yes	No	Remarks
Can explain the objectives of packaging			
Wrap according the WI			
Knows how to control a container			
Knows what to do if the container is not conform			
.....			

This document
is recorded





TIME TO SUMMARIZE!



What is a well managed CSSD?

- Professionalism of the staff
- In-site training programs
- QMS
- Organisation & optimisation
- Independance from clients - responsibilities of clients and supplier are well defined



The profile of the CSSD manager



Management & leadership skills

- Human resources (recruitment, education, assessment, occupational health & safety)
- Quality management principles and risk assessment, process validation principles
- Project management
- Activity monitoring, key performance indicators (KPIs)
- Budget and administrative
- Productive dialogues with stakeholders

Technical knowledges:

- Device reprocessing principles and technologies (chemistry, equipments, traceability)
- Microbiology and hygiene
- Surgical activities and various categories of medical devices
- Architecture, air, water quality
- Regulation, standards and guidelines

Motivation



CSSDs managers are KEY for improvement

Their role is evolving and becoming more complex, requiring solid skills in a number of areas

- Necessary to acquire the missing skills or set up partnerships or leave these positions to more experienced profiles.
- Are you ready to take up this challenge and drive change?



'Change is never easy,
but always possible'

Obama

'To change the world,
we have to start by
changing ourselves'

Gandhi

'You may not be
responsible for the
situation you find
yourself in, but you will
be if you do nothing to
change it'.

Martin Luther King

'Power is the ability to
effect change '

Martin Luther King

'Embarking on a new path is
frightening. But with every
step you take, you realise
how dangerous it was to
stand still'

Roberto Benigni

'The measure of
intelligence is the
ability to change'.
Albert Einstein





2003



2013



Future?

- topic of the coming session
- futur is about connectivity and sustainability
- made of multiple challenges
- HR have an essential role to play: be prepared !



Thank you for your attention

Hope you've filled your to-do list for the coming months 😊

