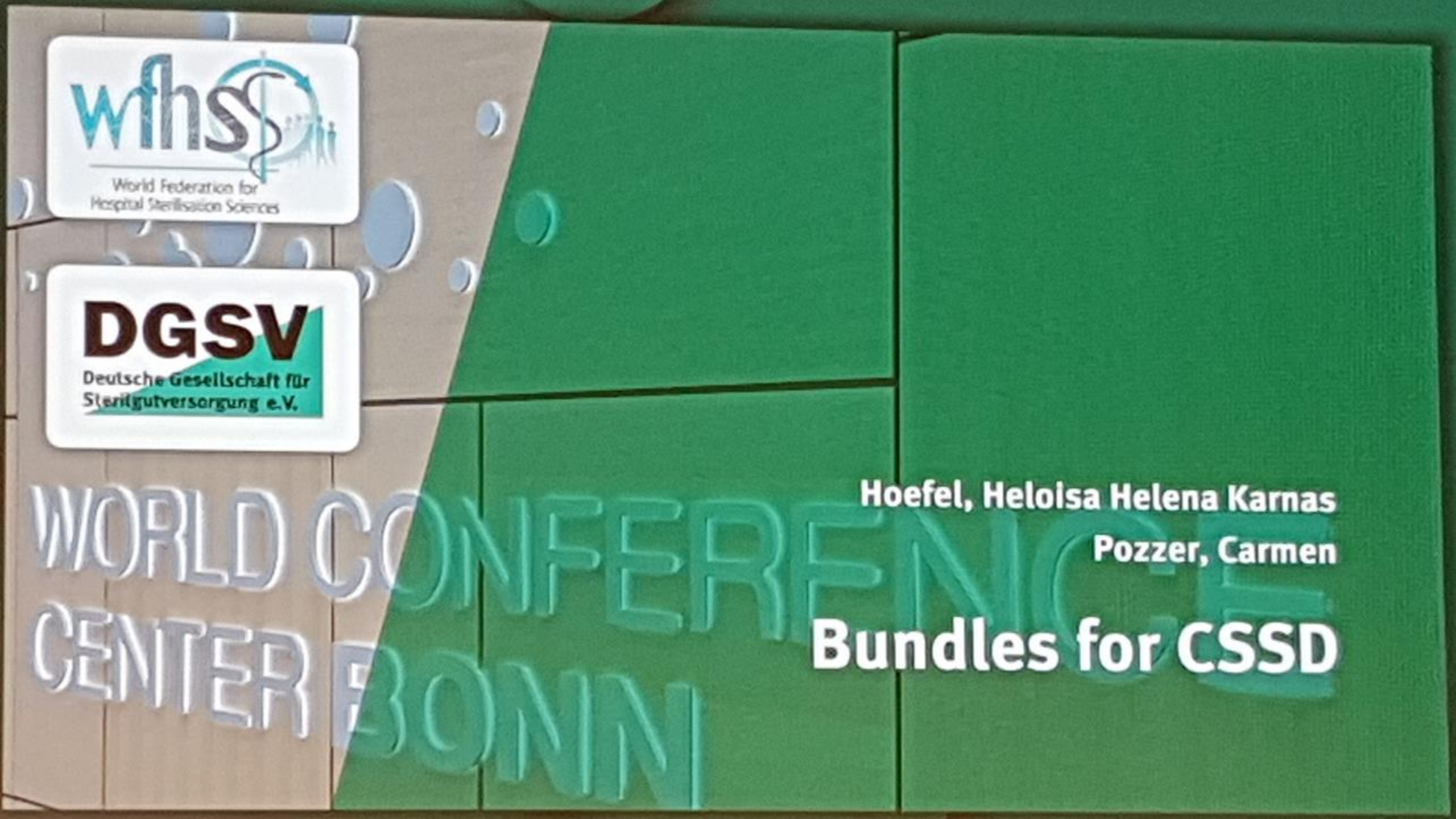
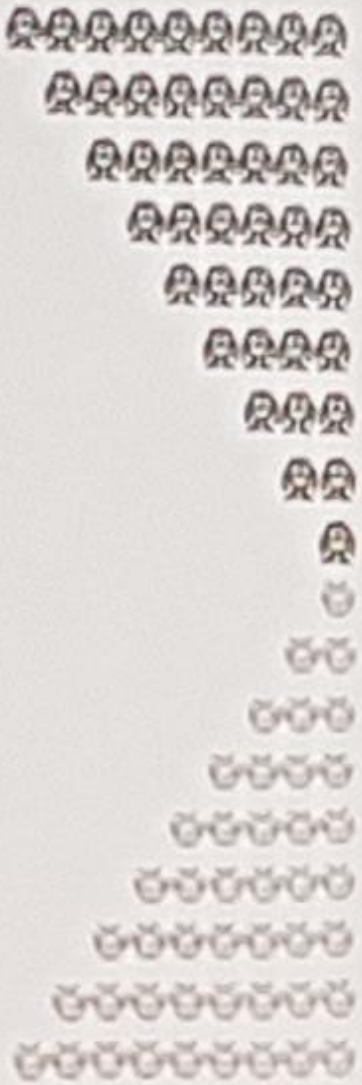


Hoefel, Heloisa Helena Karnas
Pozzer, Carmen

Bundles for CSSD



- Sterilization - the logarithmic organisms reduction → parametric indicators / it is based on how the microorganisms can grow
- Adverse conditions → they may not be able to grow
- The complexity and volume of what we know about it, goes beyond our individual ability to ensure correct and safe actions in daily activities[1]

1 Gawande A. The Checklist Manifesto. Penguin Books Ltd. London. 2010

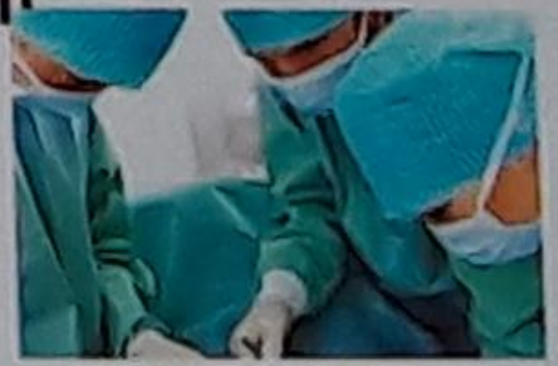
- **Expert professionals → many routines according to: scientific rationality, how they learn by generation, the law, and their practical experiences**
- **We need more researches about those practices/to produce robust evidence to prove their efficiency[3]**

3 Thiede B, Kramer A. Evaluation of reprocessing medical devices in 14 German regional hospitals and at 27 medical practitioners 'offices within the European context–consequences for European harmonization. GMS hygiene and infection control. 2013;8(2).

- Surgical Infection prevention requires integration of a range of measures → device reprocessing and sterilization is one
- WHO's prevention SI guidelines → same gaps[4] abo decontamination evidences
- Reprocessing routine is complex
- Administrators usually doesn't have enough knowledge about it
- But we have to show how it works!

4 World Health Organization. Global guidelines for the prevention of surgical site infection. WHO; 2016

- Check lists, equipment controls and other resources are widely used in CSSDs, as much the experts know, to not lead to post surgical complications
- It is almost impossible to relate SI to sterilization failure if a CSSD is well managed
- Bad surgical technique[5] can be the main reason for SI!
- Infection control (IC) team knows it



[5] Leaper DJ, Tanner J, Kieman M, Assadian O, Edmiston CE. Surgical site infection: poor compliance with guidelines and care bundles. International wound journal. 2015 Jun 1;12(3):357-62.

- **IC →variety of resources to increase health care workers' preventive measures compliance**
  - use different types of outcomes and processes indicators/ to demonstrate their effectiveness for quality assessment teams
  - Bundle is IC process indicator
- **Bundles [6] are straightforward sets of evidence-based practices that / when performed collectively and reliably, have been proven to improve patient outcomes in infection control**

6 Resar R, Griffin FA, Haraden C, Nolan TW. *Using Care Bundles to Improve Health Care Quality*. IHI Innovation Series white paper. Cambridge, Massachusetts: Institute for Healthcare Improvement; 2012.

- Bundles for CSSD could help prove processing measures compliance, avoid failures and provide safe device usage
- Other resources are not excluded!
- To evaluate bundles, processing steps could help to assure good practices and prove that bad outcomes could not be implicated to CSSD's practices (when CSSDs are properly managed)

- **The objective of this study was to develop bundles for CSSD according to experts' opinion**

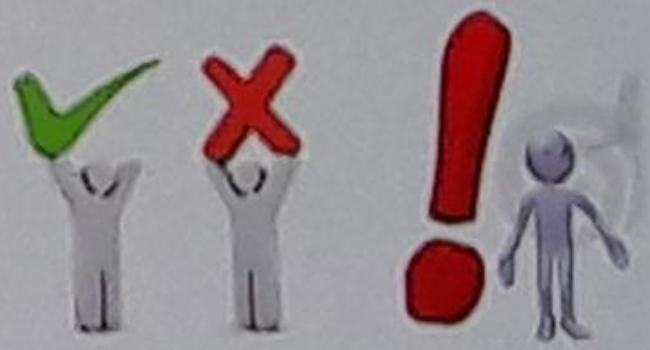
- **We did a development study using Delphi [7] modified technique to know experts opinions**
- **Participants: 8 recognized experts in sterilization field**
  →convenience sample
  →at least four years working in CSSD field
  biologist, engineer, 6 nurses (professor,government,national nursing association)
  →To final evaluation, 3 more participants were included

→Exclusion: working for a HCPs selling company

7 Habibi A, Sarafrazi A, Izadyar S. Delphi technique theoretical framework in qualitative research. The International Journal of Engineering and Science. 2014;3(4):8-13.

- The project was submitted to UFRGS Research Committee
- Answering the questionnaire was sign of agreeing to participate and they could decline at any moment if they wanted to
- The study was developed in 3 phases

- Phase 1→ On line panel: an open ended questionnaire was sent to participants
- Six main CSSD processes lists essential procedure steps in device processing
- Each element (bundle propose) was based on current scientific references when available
- They would analyze each step and answer if the element is indispensable for systematic evaluation
- Suggestions and justify



- Phase 2→ A new document with all participants suggestions were sent to all participants
- Each suggestion was justified if it was or not accepted by others and coordinators
- Participants names were not included with suggestions

- **Phase 3→ The lists were modified including or excluding suggestions**
- **Six bundles were sent to participants**
  - 5 Likert scale (total agreement, agreement, neither agree nor disagree, disagree, total disagreement)

- **To decide final inclusion of items in bundles agreements items must be from 80% of answers**
- **BUNDLES rules[6]**

6 Resar R, Griffin FA, Haraden C, Nolan TW. *Using Care Bundles to Improve Health Care Quality*. IHI Innovation Series white paper. Cambridge, Massachusetts: Institute for Healthcare Improvement; 2012.

- Each bundle can have until 5 items
- Each bundle element is relatively independent
- The bundle is used for a defined location
- A multidisciplinary team develops the bundle
- Bundle elements should be descriptive rather than prescriptive to allow for local customization and appropriate clinical judgment

Compliance will be measured using all-or-none measurement→proof of implementation

Phase 1- all participants returned opinions and suggestions.

Some justified answers saying: I don't see any influence on the work or not available to use

- ✓ Very specific masks/ aprons details, detergents characteristics, commercial indicators→ Bundles may not be prescriptive
- ✓ 5 items were not modified because they are ruled by law
- ✓ To remove the steam for cleaning lumens→ accepted. It was considered to include later. There is little availability in the country
- ✓ Thermal comfort operator→ it was maintained because even if not robust, there is evidence of impact on the results of HCW research

Phase 2 - after receiving the document containing suggestions from all, no participant sent any new comments.

Phase 3- 389 answers were evaluated in 6 bundles

- **There was experts agreements (agree or total agree) on 366 (94.1%) items in all phases**

Table 1- Total bundles agreement, disagreement, nor agree neither disagree 2017

	Agree		Disagree		Nor/neither		TOTAL
TOTAL	366	94.1%	12	3.1%	11	2.8%	389

- **11 (2.8%) neither agree nor disagree.**
- Disagreements were 12(3.1%)
- **Disagreements were the same initial opinion in phase 1**

All had from 90% agreements (agree or total agree)

- **Sterilization bundle didn't have any disagreement**

Table 2- Bundles agreement and disagreement, 2017

BUNDLES	Agree	%	Disagree	%	Nor/neither	%	TOTAL
Cleaning 1	62	93.9	3	4.5	1	1.5	66
Cleaning 2	65	98.5	0	-	1	1.5	66
Inspection	50	90.9	3	5.5	2	3.6	55
Prepare/pack	71	92.2	3	3.9	3	3.9	77
Sterilization	64	97.0	0	-	2	3.0	66
Storage/general	54	91.5	3	5.1	2	3.4	59

$p < 0.05$ $\chi^2 = 4.6949$

- **The results were not significant**

Final BUNDLE lists

= One participant disagreement

1. Cleaning pre-requisites bundle

1. Pre-cleaning removing **visible dirt after use** evidence.
2. **Personal Protective Equipment** correct use for the activity (Technical barrier)
3. Automated cleaning equipment **preventive intervention scheduled, recorded** systematically.
4. **Qualification equipment signed** by the CCSD **responsible** professional
5. Detergent **solution disposal** after each use evidence.
6. Cleaning and disinfection of surfaces carried out systematically **according to written protocol.**

2. Cleaning process bundle

1.Compatible cleaning supplies and devices

2. Detergent intended for HCPs with date of opening recorded.

3. Purified water used for rinsing products(recorded control/drinking standards).

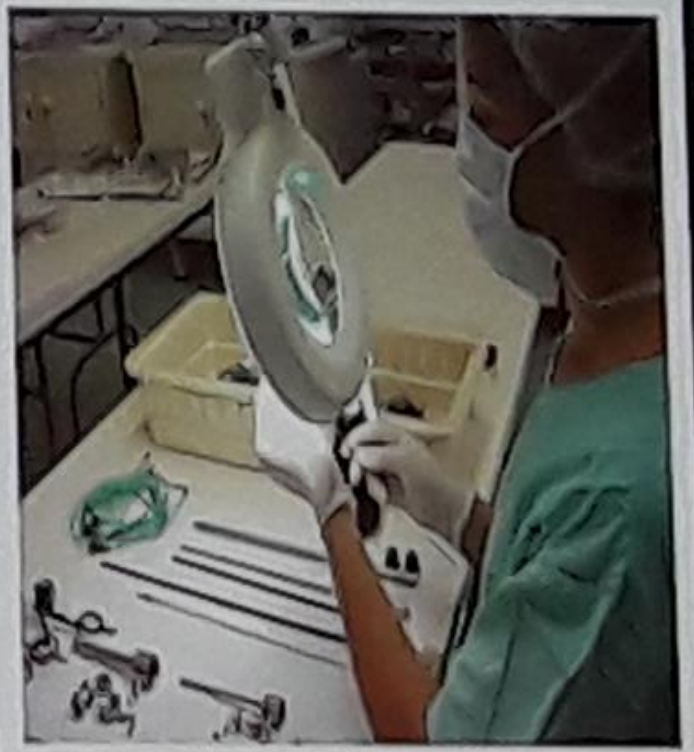
4.Cleaning/drying cannulas specific equipment.

5. Complex HCPs disassembly and manual cleaning evidences.

6. Cleaning verification tests with defined periodicity by the institution.

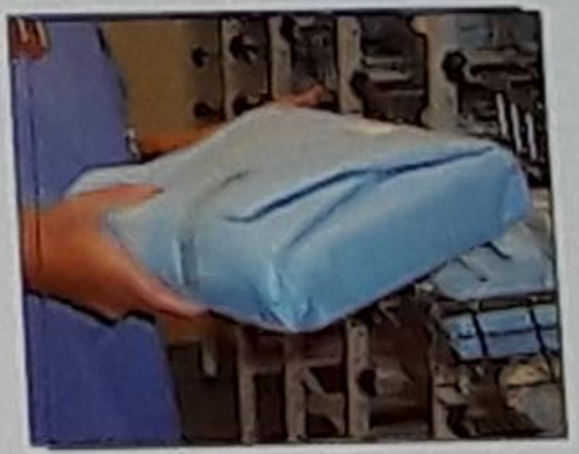
3. Inspection bundle list

1. Professionals visual acuity annual evaluation and 6/6 months from the age of 40 years.
2. Intensifier lens with lamp or microscope / stereoscope for devices with difficult-to-see details, cleanliness and integrity inspection.
3. Compressed air jet equipment to detect residual dirt in lumens on white absorbent fabric or paper at the same time for completeness of drying.
4. Articulated instruments lubrication with specific non-oily product to improve the HCPs performance.
5. Evidence of protocol use to clamps, needle holders, scissors' test functionality.



4. Preparation and packaging bundle list

1. Mask, cap and gloves used on the area.
2. Standardized Sterile Barrier System packing used according each device type.
3. HCP is suitably packed with properly folds or sealed in a sealer, or in specific sterilization containers.
4. Preventive scheduled intervention sealers recorded.
5. Product name label identification (batch number, sterilization date, deadline, sterilization method, preparation product person name) that enables traceability.
6. Kit checklist to use each time you prepare each one.
7. Surface cleaning and disinfection according to the routine established by the CSSD flow evidence.



5. Sterilization Bundle list

1. Parametric indicators (temperature, time, pressure) chemical (Bowie Dick at least) and biological and/or process specific printed registration, of each sterilization cycle phases checked and signed by the responsible professional .

2. Chemical indicators type 1 (test tape), integrity, humidity, packaging conditions checked, with records before removing HCPs from the autoclave rack.

3. Thermal comfort area for the operator.

4. Schedule and registry of corrective, preventive and qualifying sterilization equipment

5.Schedule and registry cleaning equipment as well as clean and preserved equipment.

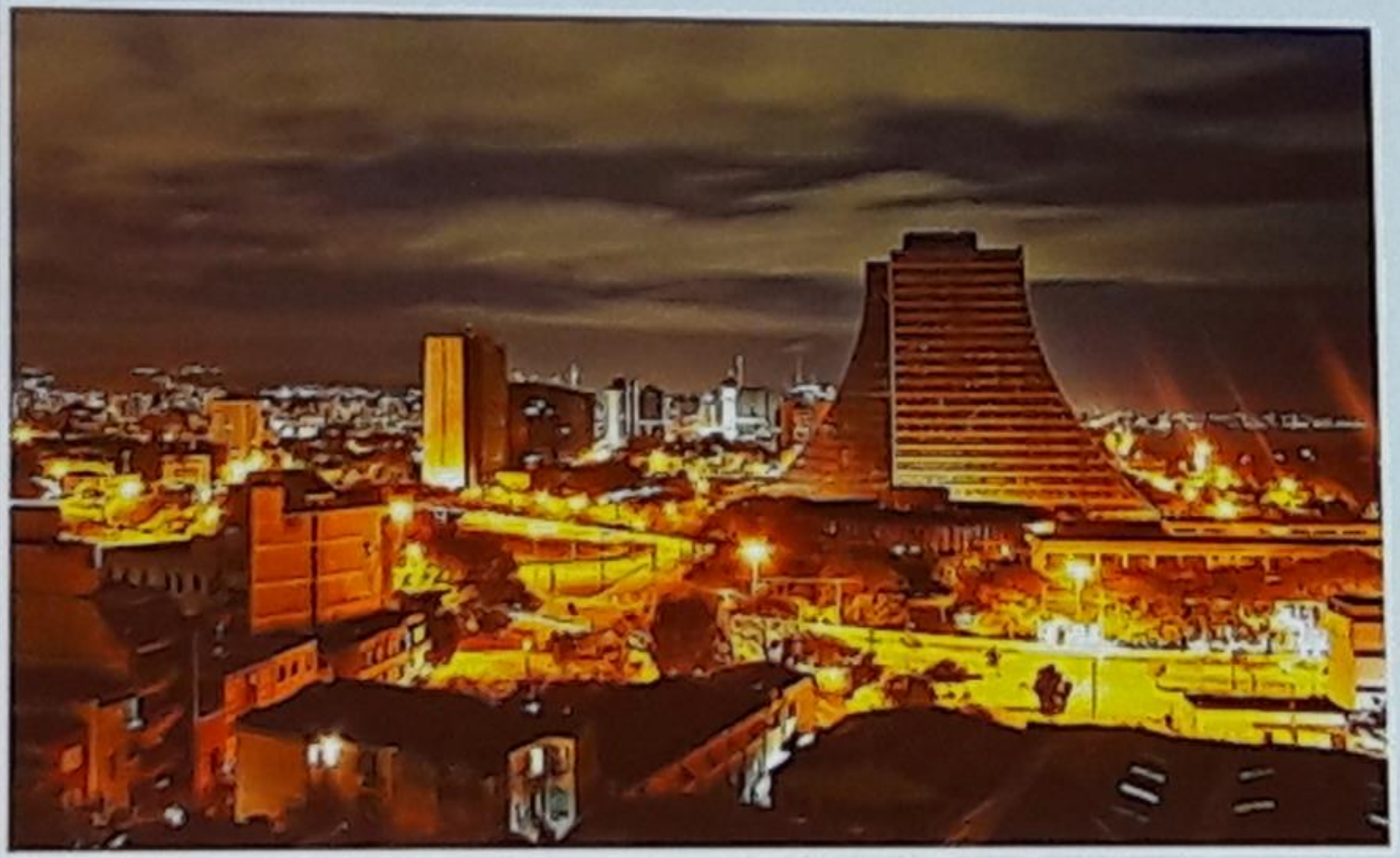
6. Standardizes load prepared as in the performance rating evidence.

6. Storage and general aspects bundles

1. Packs integrity checked before storing and at the time of distribution.
2. Clean and dry storage location without stacking (containers can be stacked) and easy access and identification.
3. Clean and dry storage location outside the CSSD in care units.
4. Disposition of stored HCP so as not to damage HCP pack.
5. Ergonomic furniture and thermal comfort throughout the CSSD.
6. Evidence that people's traffic is limited and HCPs have minimal manipulation.

- Six bundles were developed from the initial evaluation → there were included elements considered essential by the experts for safe use of products

- The bundles will be tested in a new study which will continue to show the qualifying evaluations process in CSSD and prove how quality processes are done in CSSDs facilities
- Bundles must be flexible. They can be modified for specific CSSD team's needs and according to country laws.



• OBRIGADA!

DANKE!

2017

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