Economic comparison of steam sterilization quality assurance policies in German and in Chilian hospitals

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Conflict of Interest Statement

No conflict of interest

No affiliation, no direct or indirect financial benefit from any company or organization that promotes either sterilization Indicators, electronic measurement systems or validation services.

Background

- **How can we measure** that a load coming out of a steam sterilizer is actually sterile – thus free of any viable microorganisms?




We cannot…

But we need a method that generates trust that each load item sterile!

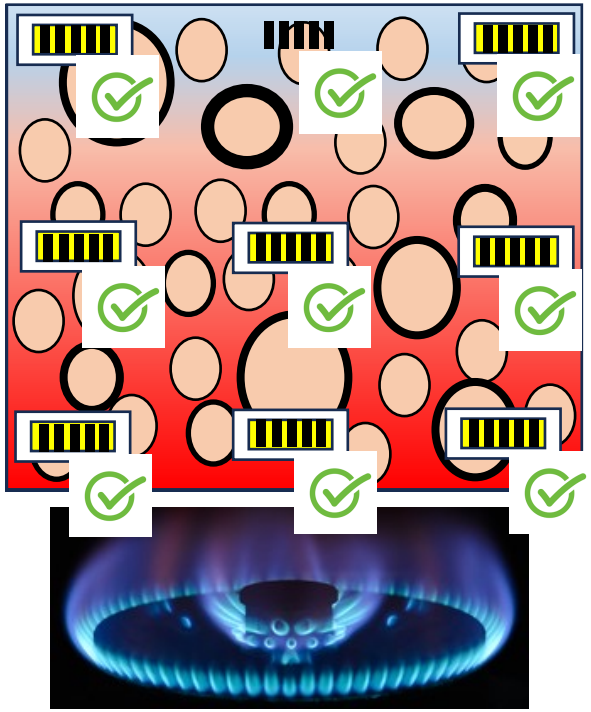
Background

Sterilizing a wide variety of medical devices in a hospital can be compared to cooking different combinations of a wide variety of eggs with different sizes, shapes, thickness of the shell. We want to make sure that all eggs are completely cooked through.

A) Indicator-based QA

Will design an **indicator**, that changes the color under the conditions under which the most difficult to cook eggs are well cooked.
In every cycle this egg-cooking test body will be cooked with the egg and checked in the end before releasing the load.

… but maybe it would be better to put in 3 on the top layer to be safe? Or maybe better 6 distributed to be even safer… or maybe better 9….?

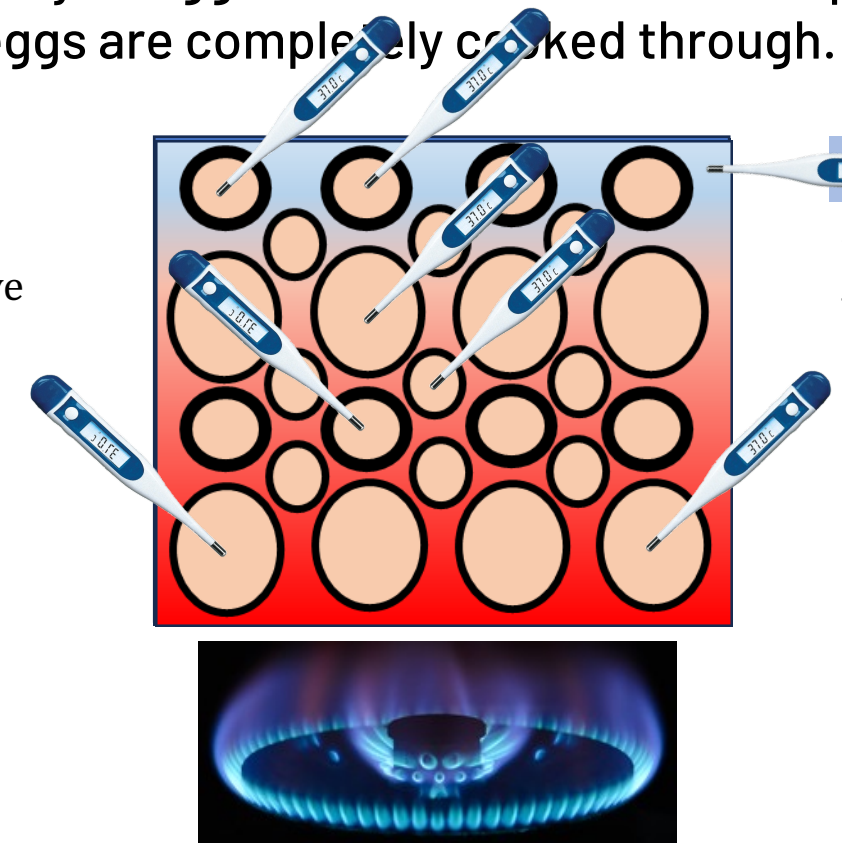


Conclusion: Placing a sufficient amount of Indicators that represent a difficult egg to reference positions in the cooking pot can generate trust that all eggs in a mixed load are well-cooked.

Background

Sterilizing a wide variety of medical devices in a hospital can be compared to cooking different combinations of a wide variety of eggs with different sizes, shapes, thickness of the shell. We want to make sure that all eggs are completely cooked through.

performance qualification
PQ
process of establishing by objective evidence that the process, **under anticipated conditions**, consistently produces a product which meets all predetermined requirements
[ISO 11139:2018, 3.220.4]



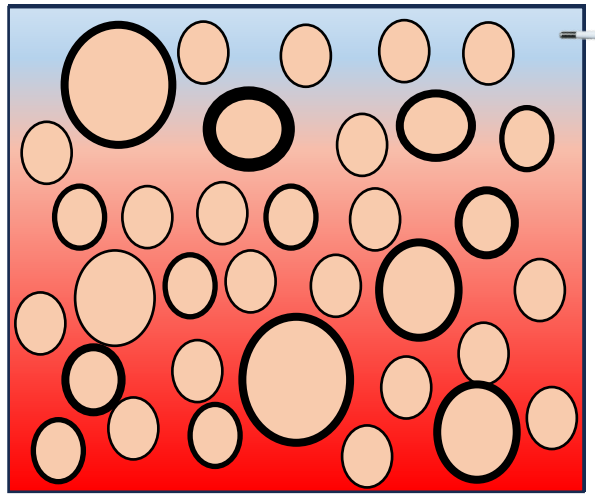
B) Validation-based QA

Will perform a test with the pot full of only the most difficult to cook eggs and measure the exact temperature distribution in the pot, that lead to all «worst case eggs» to be fully cooked.

Background

Sterilizing a wide variety of medical devices in a hospital can be compared to cooking different combinations of a wide variety of eggs with different sizes, shapes, thickness of the shell. We want to make sure that all eggs are completely cooked through.

Conclusion: Validating that a certain cooking process, leads to good results even if the worst case combination of difficult eggs is cooked generates trust that the same cooking conditions will also lead to success for any other combination of eggs.
Verifying that a given cooking cycle has identical parameters as in the successful validation cycles generates trust that also this specific cycle generates only well-cooked eggs.



B) Validation-based QA

Will perform a test with the pot full of only the most difficult to cook eggs and measure the exact temperature distribution in the pot, that lead to all «worst case eggs» to be fully cooked.

Then in every production cycle it will be verified that the worst-case-egg cooking parameters from the validation were met. This is called **parametric release.** Indicators are not necessary. But some people like to put **just one single indicator – just in case** the thermometer is broken.

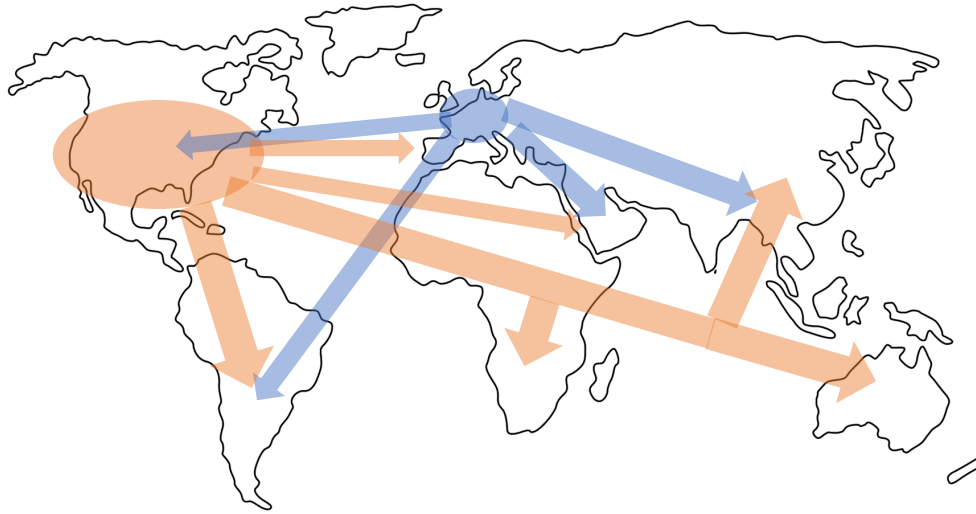
Background

- For MD steam sterilization in hospitals both methods – indicator and validation-based – are currently used, and each method is dominant in different regions.

- A) Indicator-based process quality assurance ...was developed in the US is reflected in FDA/AAMI regulation and is now the predominant QA model in North and South America, parts of Asia & parts of southern and Eastern Europe

- B) Validation-based process quality assurance ...was developed in England, France, Germany is reflected in EN and ISO standards (e.g. EN 285 & ISO 17665) and is the predominant QA model in DE, FR, UK, AT, CH, NL, Scandinavia

Pharma: GMP validation everywhere....
But Hosptial daily practice....



Mission Statement

The WFHSS dedicates itself to the promotion of the worldwide harmonization of sterilization departments and of decontamination practices especially by providing:

- a meeting place for national and regional non-profit sterilization societies, thus stimulating cooperation and the exchange of information and best practices;
- information via its website to all our stakeholders and interested parties.

In this way we make a contribution not only to ensure that the quality of reprocessing is of the highest possible level across the globe but also to make the basic right of every patient to be treated with a medical device of a good quality come true. Integrity and objectivity, openness and transparency, cooperation and support are the core values in our organization.

Wim Renders
Honorary President

Goal of the Research

Having two different system of course raises the question:

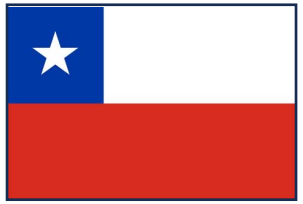
Which system is better in which context?

The suitability of a quality assurance system can be judged in terms of

- **Risk reduction** (How well does the system protect from undesired events)
- **Smooth Work flow** (How much effort in involved in enacting the system in daily life)
- **Cost efficiency** (How high are the total costs of a system)

The goal of this research is to help policy makers by contributing to an objective comparison between System A & System B focusing on the third factor of **cost efficiency**

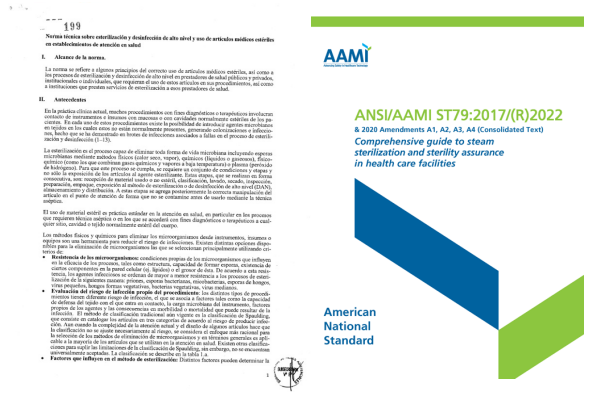
METHODS



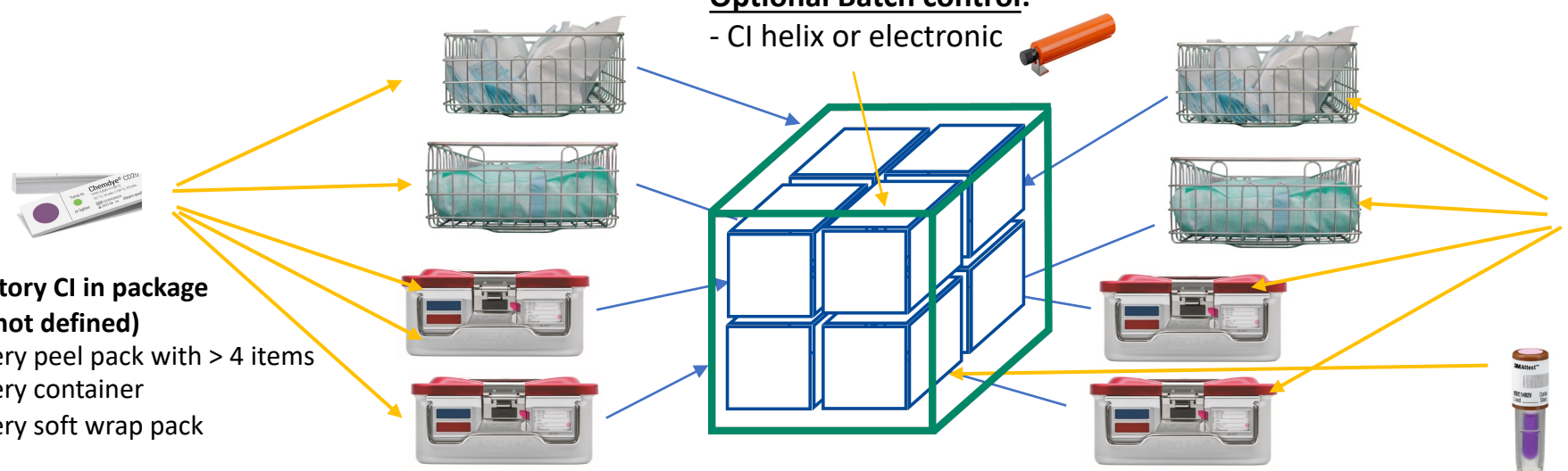
- Two representative countries were chosen, Chile as example for system A and Germany as example for System B
- **Regulations** for steam sterilization were analyzed in a literature research to determine minimum requirements and regulatorily recommended or possible variations in both countries
- **Surveys and semi structured interviews** with **20 Hospitals** (10 Chilean and 10 German)
- **Cost analysis** by using real world data from surveys, combined with publicly available purchase data and prices from www.mercadolibre.cl
- To make the data be comparable costs from different hospitals were “normalized” to a generic 8 STU sterilizer with 2500 yearly cycles with mixed loads. That way comparative QA-spendings could be calculated for every hospital and averages made per group and per country.

Requirements and Variations Chile (A)

- Chilean Ministery guideline 199, based on AAMI ST 79
- Chilean "Norma 199 ", 9 March 2018, based on AAMI ST 79
- EN 285 is not mandatory, (but most still had EN 285 copliant sterilizers)
- Clean steam from DI water not mandatory but very common
- Daily vacuum test and BDT



Optional Batch control:
- CI helix or electronic



Mandatory CI in package (Type not defined)
– in every peel pack with > 4 items
– in every container
– in every soft wrap pack

Options: CI (Type 4/5 or 6):
– in every peel pack
– in every container (per level)
– in every soft wrap pack

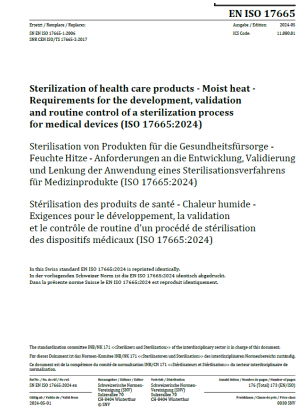
→ **Load release is based on a combination of control of parameters and indicators**
→ **OR personnel is used to "verify sterility" via inside indicators**

Mandatory BI
– weekly
– in every load with implants
– after service intervention

Optional:
– BI with or without PCD
– daily or even more often

Requirements and Variations Germany (B)

- Robert Koch Institute KrinKo BfArM 2012 Guidelines
- EN 285 mandatory (→ clean steam from DI water mandatory)
- MPBetrVO → mandatory validation yearly (EN 285, ISO 17665)
- Batch control is not mandatory, but it is relatively common as routine control (generally PCD with CI, or increasingly electronic/integrated into Sterilizer
- Regular vacuum test
- Daily BDT test

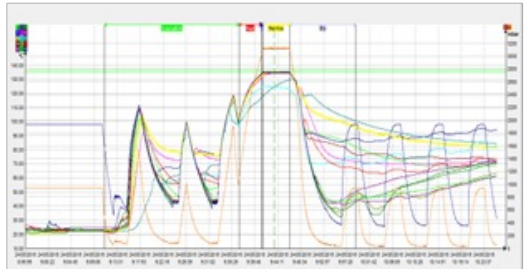

EN ISO 17665

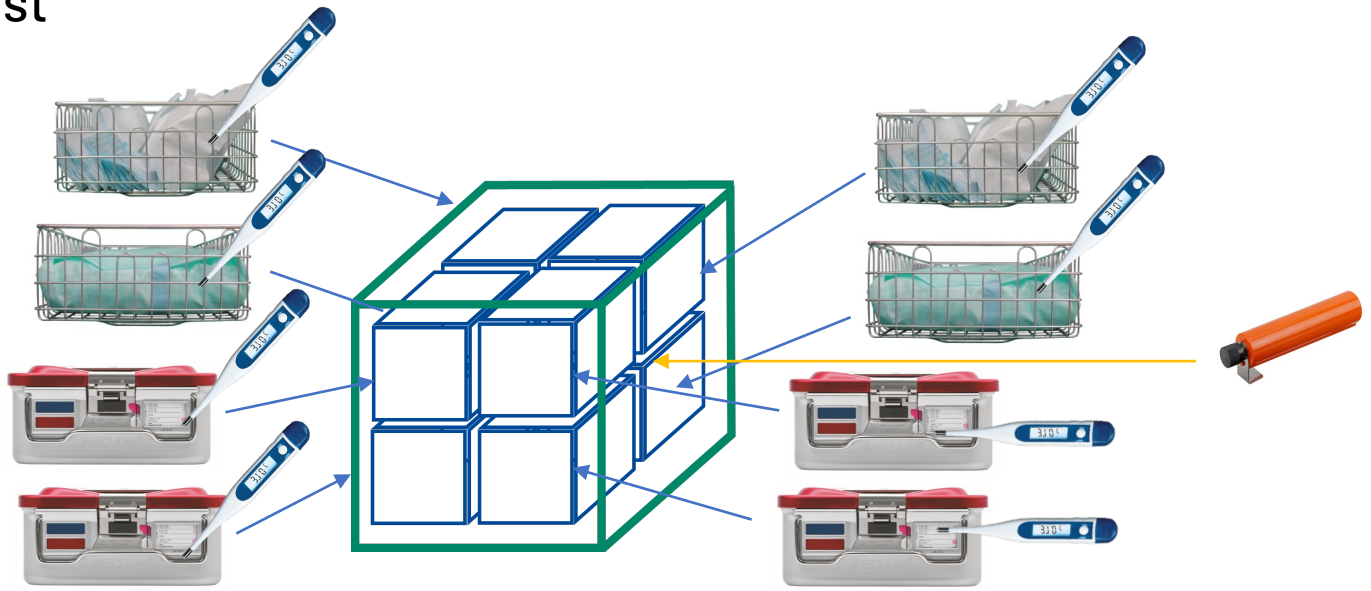
Sterilization of health care products - Moist heat - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 17665:2024)

Stérilisation des produits de santé - Chaleur humide - Exigences pour le développement, la validation et le contrôle de routine d'un procédé de stérilisation des dispositifs médicaux (ISO 17665:2024)

Process Validation

…and yearly re-qualification





Optional Routine Control:
Typically helix PCD with chemical indicator or integrated in the sterilizer as routine monitoring tool

→ **Load released is mainly based on reference to validated parameters (“parametric release”)**
→ **OR personnel relies uniquely on outside (mostly type 1) indicators**

Regulatory Requirements Germany (B)

Installation & training of SOPs

IQ OQ PQ

Technical Service RQ

Technical Service RQ

Validation

Requalification

Requalification…

PQ with worst case & minimum loads

Routine use: parametric release validated parameters

Routine use: parametric release validated parameters

Typical Loads

Typical Loads in Chile

- Indicators 4/5/6 in every load unit

Biological Indicator Test Pack.

- once a week
- with implants
- after repairs

Typical Loads in Germany

- No chemical nor biological indicators
- Optional Helix Test

Results

Chilean and German CSSDs

- 23 Hospitals in total, 13 Chilean, 10 German
- Average CSSD Size, capacity, number of cycles are very comparable
- Slightly higher STU/y in Chile (less reserve capacity)

		Sterilizers	No. of Sterilizers	# STUs	cycl/steri	STU/y	Clean Steam
H1	PU	2x8 stu	2	16	2'500	25'000	x
H2	PU	4x 12	4	48	2800	134'400	x
H3	PU	2x8, 2x10 stu	4	36	1'450	52'200	-
H4	PU	3x9, 1x6 stu	4	33	1'650	54'450	x
H5	PR	3x12 stu	3	36	2'600	93'600	x
H6	PR/EX	3x9 stu	3	27	1'800	50'000	x
H7	PR	1x8, 2x6	3	20	1'200	55'000	x
H8	PR	1x12, 2x8, 1x4	4	32	1'451	54'000	x
H9	PR	2x12 stu	2	24	2'170	41'000	x
H10	PR	1x8, 2x4 stu	3	16	4'095	65'524	x
H11	PR	2x8 stu	2	16	2'760	46'000	x
H12	PR	1x9, 1x5 stu	2	14	3'000	85'000	x
H13	PR	1x8, 1x4 stu	2	12	3'726	44'716	x
Total:	4 vs 9		38	330	31'203	800'890	12/13
Average:		8.68	2.9	25.4	2'400	61'607	92%

	Sterilizers	No. of Sterilizers	# STUs	cycl/steri	STU/y	Clean Steam
H1	3x8 stu	3	24	1'358	29'000	x
H2	3x9 stu	3	27	3'778	102'000	x
H3	3x9 stu	3	27	3'630	98'000	x
H4	2x8 stu	2	16	2'250	36'000	x
H5	2x6 stu	2	12	1'300	13'000	x
H6	3x8 stu	3	24	930	18'700	x
H7	2x9, 2x6 stu	4	30	1'115	33'000	x
H8	3x9 stu	3	27	2'230	80'000	x
H9	3x6 stu	3	18	1'785	32'124	x
H10	2x4 stu	2	8	2'100	14'000	x
Total:		28	213	20'475	455'824	10/10
Average:	7.61	2.8	21.3	2'048	45'582	100%

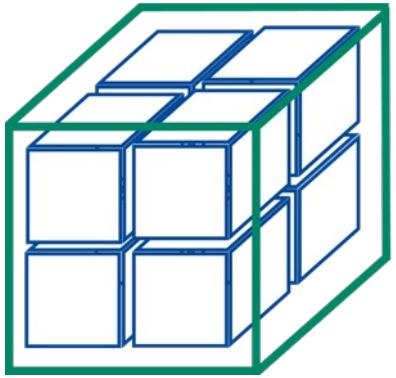
→ Reference Sterilizer: 8 STU & 2500 cycles/year

Reference Sterilizer and Calculation

- For better comparison, consumption values and costs of all hospitals were normalized to a reference sterilizers of 8 STU and 2500 cycles per year

Example Hospital: 1x12 & 1x8 STU
Avg Sterilizer 10 STU
1500 Cycles/year

BDT:	500	USD/ year
CIs:	1500	USD/ year
BIs:	1000	USD/ year
Total	3000	USD/ year



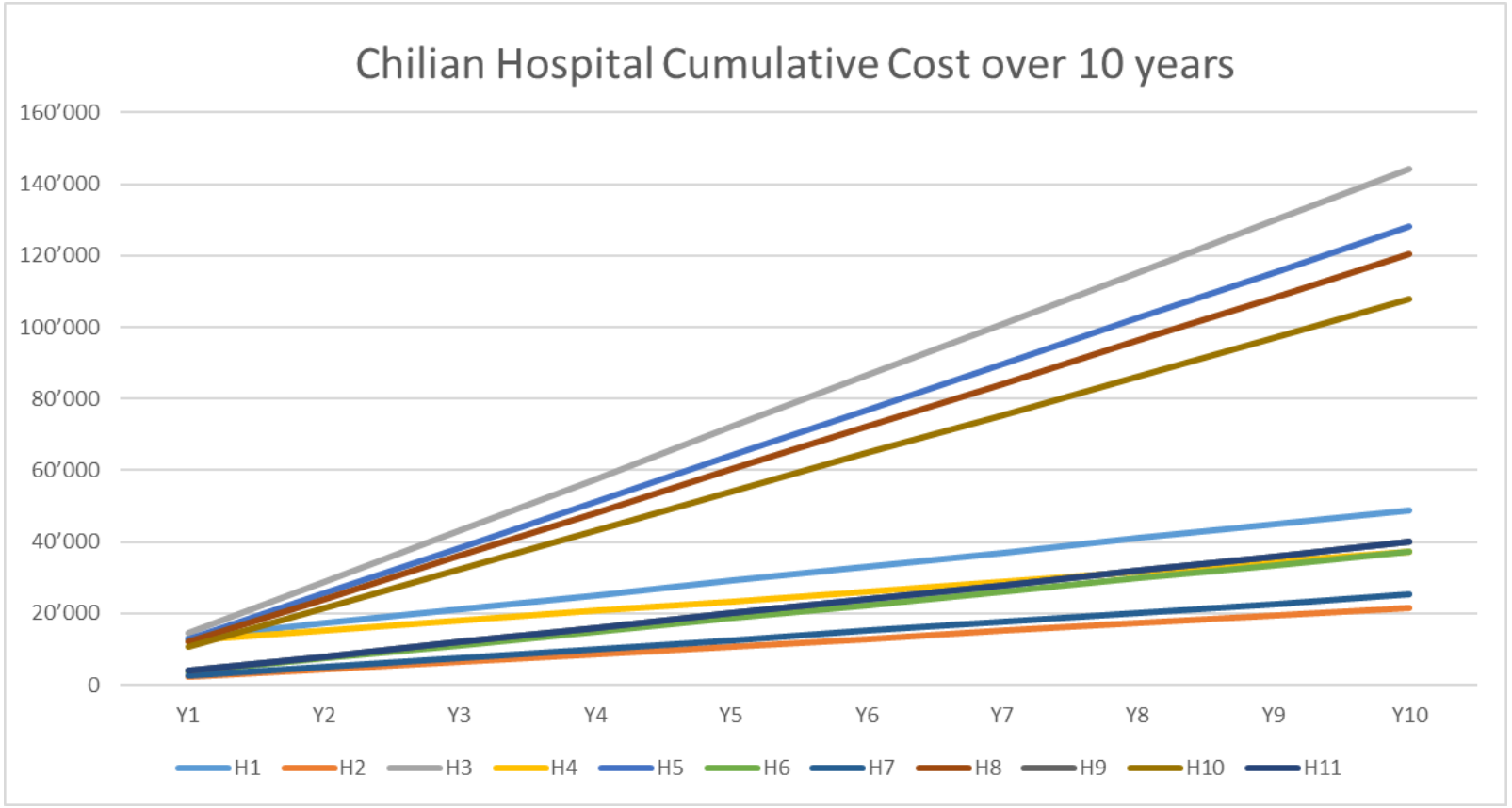
Normalization Factor:
- For Sterilizer Size: x 0.8
- For cycle difference: x 1.67

Normalized to reference sterilizer
Avg Sterilizer 8 STU
2500 Cycles/year

BDT:	500*	USD/year
CIs:	2000	USD/year
BIs:	1250**	USD/year
Total:	3750	USD/year

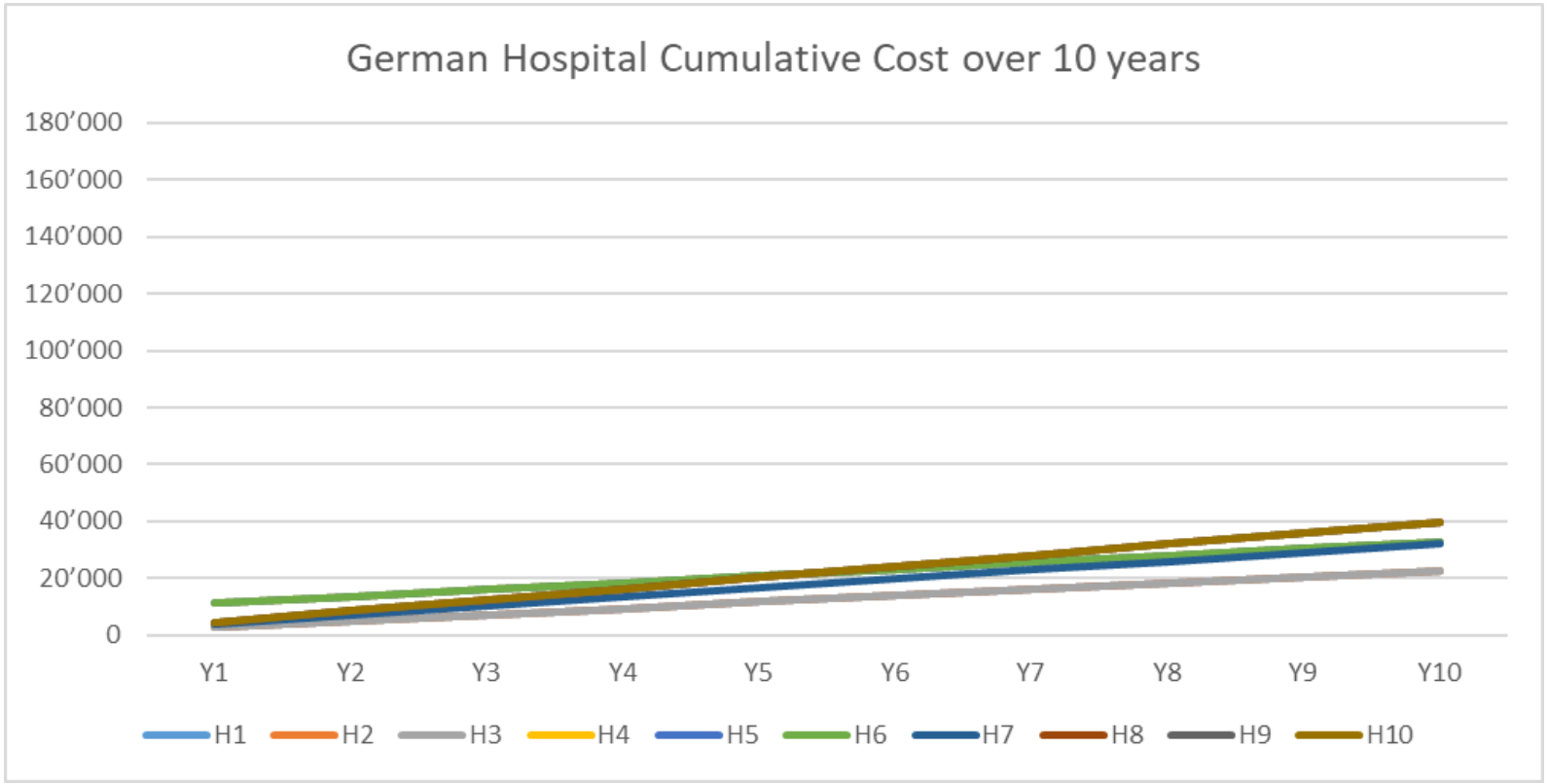
*BDT does not change because 365 BDT/ year don't depend on # of cycles nor size
**Additional correction accounting for 52 BIs / year independent of # cycles and size. Rest of Bis due to use policy and # of implants

Quality Assurance Cost System A



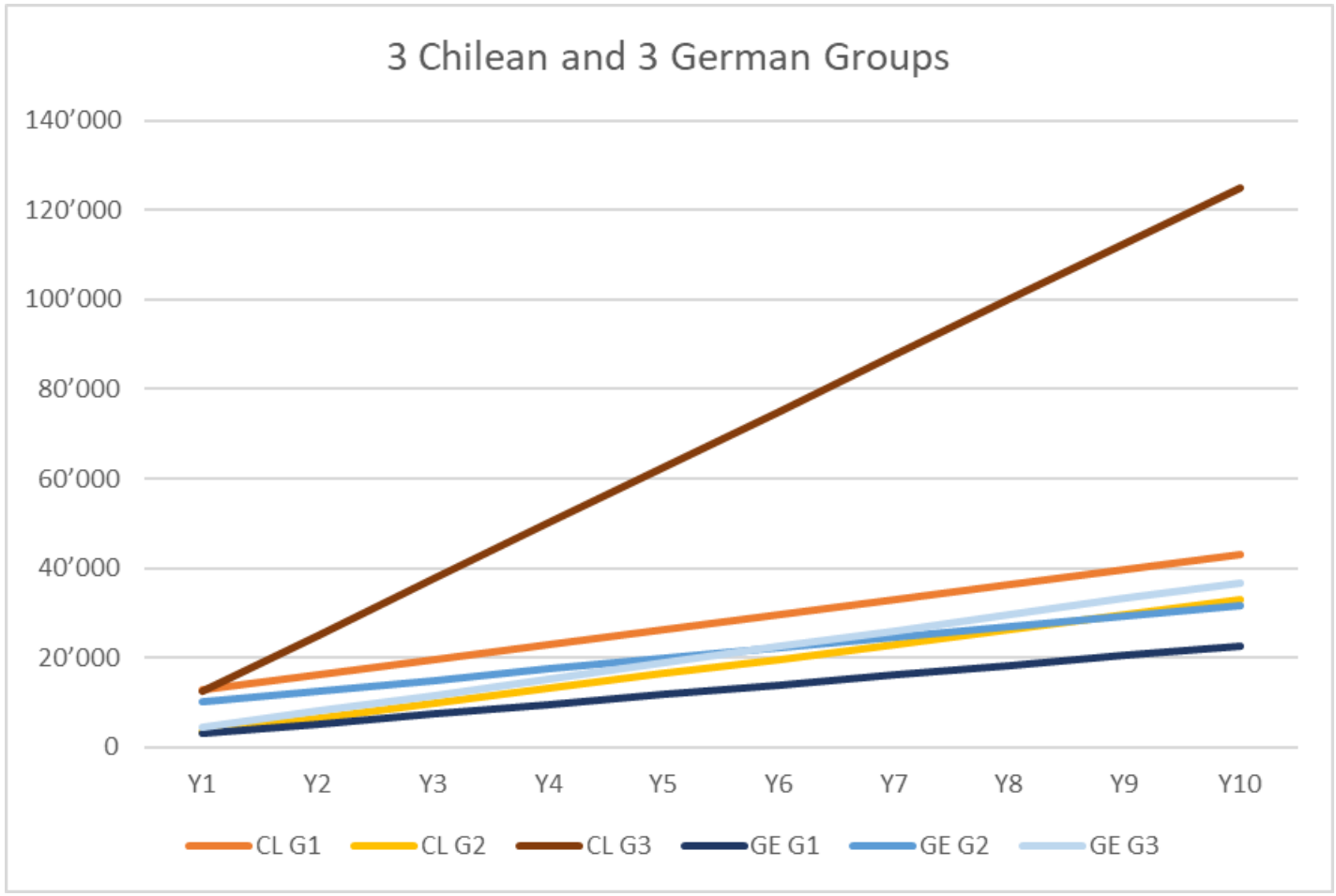
- Very high degree of variation of type of products for the same purpose (e.g. type 4 vs type 5, BI variations, BDT variations)
- Large difference between hospitals
  ~2'500 – ~15'000 USD p.a.
- Private clinics spend more than public hospitals
- Average cost 7'550 USD/ 8 STU sterilizer with 2500 batches
  → **0.38 USD per STU**

Quality Assurance Cost System B



- Lower degree of variation of type of products for the same purpose (BDT and Batch control)
- Low cost range between hospitals 2'300 – 4000 USD p.a.
- Cost differences depend on
  - integrated electronic BDT?
  - Batch control in every Batch?
- Average cost 3'200 USD/ 8STU sterilizer with 2'500 batches
  → 0.16 USD per STU
  → 71% lower average cost than in Chile

Comparison System A vs System B



- **3 Groups per country**
  - Group 1 – Regulatory Minimum
  - Group 2 – using integrated option
  - Group 3 – overcompliers
- **CL1 vs GE1**
  → Minimum in Germany (Validation ~2000 USD/year + BDT) is lower
- **CL2 vs GE2**
  → integrated test costs are the same, but in Chile regulation requires Indicators on top, higher cost
- **CL3 vs GE3:**
  → in Germany costs are capped (1 helix test) while they can become unreasonably high in Chile due to "more is better" logic of System A

Discussion

- System A has no clear definition of what is safe enough. There is always uncertainty. Which results in wide spreads in indicator spending based on how much budget is available and therefore "perceived safety" between rich and poor hospitals.

- System B has a clearer definition of what is "sufficiently safe".
  As a consequence everyone is following the same practice and there is no difference in the safety standard between "rich and poor hospitals".

- System B: more batches / same cost System A: more batches linearly rising cost.

- With System B the normal price for "perfect safety" is 2'300-3'700 USD/year.
  With System A the price for the minimum compliant setup is in a similar range of 2'500-3'500 USD. There however hospitals may not feel that they have a perfectly safe system, compared to other hospitals who spend more. Therefore, System B will generally give more peace of mind to the CSSD department

- SAVING POTENTIAL for Chilean Health System
- 400 Spitäler 3 Steris → ca 1000 Steris in Chile
  Total Kosten 7 Mio USD → 3,1 Mio USD → Saving potential of ~4 Mio/year for Chilean health system

Discussion: Direct comparison

	System A	System B
Ambiguity:	No clear definition of what needs to be done to be “save enough”	Clear definition of what needs to be done to be “save enough”
Total cost:	Total costs are a function of budget & need for higher safety perception	Costs are ~ the same for all hospitals
Cost per STU:	Total cost grows linearly with STU per year	Total cost is capped and has low or no dependence on STU/year
Workflow:	Managing & evaluating indicators is additional work step	Makes workflow leaner and more efficient
Preconditions:	Needs consumable product	Needs validation service provider

Discussion: Saving Potential

- Estimation of saving potential for Chilean Health System if it was to change from System A to system B
- There area ~400 Hospitals with an average of ~2.5 Sterilizers → ~ 1000 Steam Sterilizers in Chile
- Total Cost with current system ~ 1000 x
  Total Kosten 7 Mio USD → 3,1 Mio USD → Saving potential of ~4 Mio/year for Chilean health system

Limitations

- 13 Chilian and 10 German hospitals were analyzed. Hospitals who participated may have slightly different average than the national average, especially for Chile where the spread is very high.
- No difference was made between types of hospitals. (Public, private, Traumatological, orthopedical hospitals, e.g. Number of surgeries/day has impact on # of Bis)
- The Cost calculation was mainly based on numbers obtained by hospitals.
  Errors in number reporting cannot be excluded.
- The study was only done in two countries Chile and Germany, other countries may have somewhat different cost structures, although it can be expected that they are similar.

Further Research Suggestions

Further Research Suggestions

- Extend economic comparison to other countries (e.g. USA, France, UK, China) to get a more complete picture
- Study factor practicability more in detail
- Study factor risk reduction in non-biased way
- Come to an exhaustive comparative evaluation of system A and system B potentially resulting in a global harmonized best practice recommendation

Conclusions

- System A has an inherent uncertainty (when is safe enough?) often resulting in – if budget is available - extensive use of indicators driving costs very high.
- System B has a clear definition of "safe enough" and is overall more economic than System A considering TCO. Average saving of 60% total cost.
- None of the 13 Chilean hospitals would have a higher cost if it would switch to system B, but 9 would have a significantly lower cost (up to 75% cheaper)
- A comparison in all 3 factors (safety, cost, workflow) seems to favor System B
- Currently the interpretation of Chilean regulations are a blocker for hospitals to implement System B, because they would still have to use System A at the same time.
- It may be advantageous for Chile and countries with similar regulatory situations to at least give freedom to use either of the systems and not mandate only System A.
- Hen-egg problem with validation services. If regulations don't allow, nobody will invest.

References

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- ISO 17665-1:2006 Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
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- EN 867-5:2001 Non-biological systems for use in sterilizers - Part 5: Specification for indicator systems and process challenge devices for use in performance testing for small sterilizers Type B and Type S
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Finishing Quote

The greatest enemy of knowledge is not ignorance, it is the illusion of knowledge.

Stephen Hawking

THANK YOU
for Your Attention

And have an inspiring WFHSS Congress!!!