



A STUDY OF ESTABLISHMENT AND EVALUATION OF A RISK PREDICTION MODEL FOR STEAM STERILIZATION

Name: Xin Zhao

**Affiliation: Xuanwu Hospital Of Capital
Medical University - Beijing. China**



首都医科大学宣武医院
Xuanwu Hospital Capital Medical University

- **Established in 1958**
- **National Center for
Neurological Disorders**
- **National Clinical Research
Center for Geriatric Diseases**
- **Amount of Beds: 1643**
- **Amount of ORs: 39**



background

- Steam sterilization is still the most preferred method in hospital
- Quality control of sterilization process:
 - Professional competence of staff
 - Performance of sterilizer

“ A High level sterility assurance shall be achieved by
effective combination of human and equipment! ”

background

Sterilizer Unexpected Alarm



www.wfhss.org



Forced shutdown



Re- Sterilization



Delivery delay



Work overtime



Waste resources

background

- **24 alarms of sterilizers in total were triggered in 2021.**
- **320 packs had to be re-packed and re-sterilized due to those alarms.**

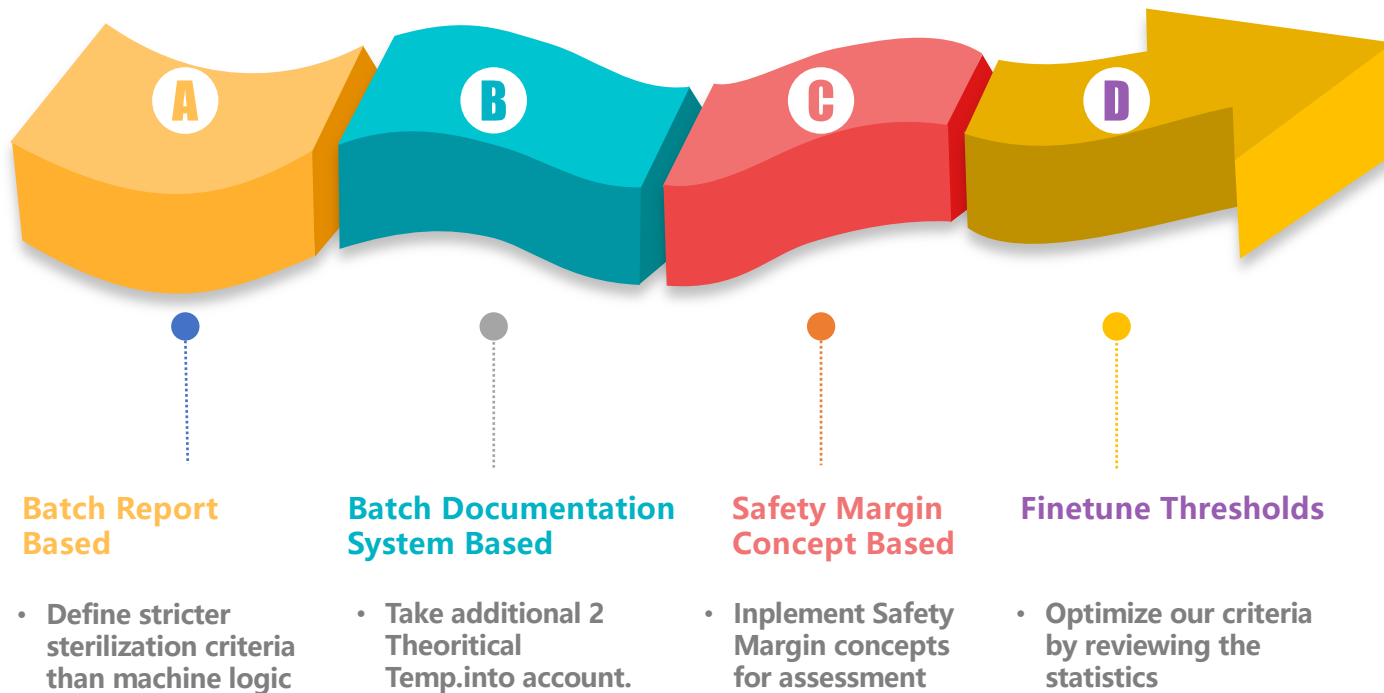
Alarm	Number of Alarm (% of Total)	Resolution
Alarm during <u>Pre-Vac</u> phase	4 (16%)	① Pressure sensor calibration ② Tighten pipings
Alarm during <u>Sterilization</u> phase	10 (42%)	Temperature sensor calibration
Alarm during <u>other</u> phases	10 (42%)	Replace PLC battery

Objective

- This experiment is an attempt to establish a sterilization risk prediction model, by applying criteria stricter than the control system of sterilizer, to proactively intervene in the sterilization process at an early stage thus provide "Early warning" of the sterilization quality.
- It eliminates the risk of failure much earlier and allows CSSD to manage the sterilizer in a proactive and predictable manner.



Materials and Methods - Experiment Group



Materials and Methods - A

➤ Object of evaluation

Selected Sterilization Program	Moment of evaluation	Parameter to be evaluated
P1 (134°C, 5min)	At completion of every batch	T1: Control temperature T2: Record temperature P1: Control pressure P2: Record pressure

Materials and Methods - A

Step 1: Read batch report carefully

Signature:
Cycle approved: Y/N Date:
CYCLE PASSED

FB value	136.8min
Time Drain above ster. temp.	5:00m:s
Max. sterilize temperature	135.1°C
Min. sterilize temperature	134.4°C

53:38 Complete	953	65.6
52:19 Air Break	58	73.4
49:19 Dry	91	89.7
47:15 Exhaust	781	64.3
45:44 Hold Air	796	70.8
44:49 Air Break	68	76.7
41:49 Dry	98	88.9
39:43 Exhaust	786	68.2
38:12 Hold Air	798	71.3
37:16 Air Break	58	74.6
26:16 Dry	91	59.3
22:08 Exhaust	3109	134.9
22:07	3111	134.9
21:07	3094	134.8
20:07	3096	134.8
19:07	3101	134.9
18:07	3124	134.8
17:07 Sterilize	3102	134.3
13:18 Heat-up	73	71.7
10:19 3. Vacuum pulse	1822	116.8
8:38 2. Steam pulse	70	52.9
5:38 2. Vacuum pulse	1808	114.7
3:41 1. Steam pulse	62	62.1
0:01 1. Vacuum pulse	998	45.9

m:s
Time Phase : 22.08.2023 / 15:31 mbara T2 °C
Cycle start

Dry time	17.0min
Sterilize temp.	134.2°C
Sterilize time	5.0min
No. of pulses	3

Set points :
Version : PR: 05.06.2008 SW: U.5.1
Cycle : 1: Instruments 134°C
Operator : User
Cycle counter : 000063
Machine type : 9-6-15 HS2 No:2005375
Department : CSSD
Hospital : XAVY-4
RELIED CYCLE DOCUMENTATION

Step 2: Understand alarm criteria

Phase	Machine Alarm Criteria
Pre-Vac	Vac Time > 15 min
Sterilization	1 Control Temp T1 < 134 °C 2 Deviation between T1&T2 > 1 °C 3 Deviation between P1&P2 > 100 mbar
Other	PLC battery running \leq 24 months

Step 3: Determine preventive intervention criteria

Phase	Preventive Intervention Criteria
Pre-Vac	Vac Time \geq 8 min
Sterilization	1 T1 or T2 < 134.2 °C 2 Deviation between T1&T2 > 0.6 °C 3 Deviation between P1&P2 > 60 mbar
Other	PLC battery running \leq 12 months

Materials and Methods - A

	Control Group	Experiment Group
Period	2021.8---2022.4 (9 Months)	2022.5---2023.1 (9 Months)
Batches	4115	4142
Evaluation and Actions	Evaluate batch report against EN285	<ul style="list-style-type: none"> • Evaluate batch report against EN285 • Implement the new preventive intervention criteria
	Only contact service whenever an unexpected alarm is triggered	<ul style="list-style-type: none"> • Contact service whenever one of the preventive intervention criteria was reached • Sterilizer still runs normally while waiting for preventive service action to be taken

Intermediate Results of Study

#	Pre-Vac Phase	Sterilization Phase	Batch No. (Sterilizer No.)	Criteria triggered Preventive Intervention	Preventive Service Action	Time for Preventive Service
1	√		752359 (#2)	1st Vac Pulse >8min	Replace hose connection	15min
2	√		3011626 (#4)	1st Vac Pulse >8min	Calibrate P sensor	35min
3	√		3011626 (#4)	1st Vac Pulse >8min	Tighten hose connection	5min
4		√	751357 (#3)	T1 <134.2°C (T1= 134.1°C)	Calibrate T sensor	40min
5		√	751357 (#3)	Deviation T1&T2 >0.6°C	Calibrate T sensor	45min
6		√	752329 (#1)	Deviation T1&T2 >0.6°C	Calibrate T sensor	40min
7		√	752329 (#1)	T2 <134.2°C (T2= 134.1°C)	Calibrate T sensor	45min

Totally 3h25min

Intermediate Results of Study - A

3-2

Signature: _____

Cycle approved: Y/N Date: _____

CYCLE PASSED *[Signature]*

F0 value	129.1min
Time Drain above ster. temp.	5:00m:5
Max. sterilize temperature	134.9°C
Min. sterilize temperature	134.1°C

66:18 Complete	949	55.4
64:59 Air Break	59	58.5
61:58 Dry	94	65.0
59:50 Exhaust	802	56.3
58:19 Hold Air	797	58.7
57:24 Air Break	59	61.3
54:23 Dry	95	67.5
52:11 Exhaust	806	60.9
50:40 Hold Air	797	63.0
49:44 Air Break	56	65.5
39:47 Dry	95	97.7

31:50 Exhaust	3079	134.9
30:50	3072	134.9
29:50	3071	134.8
28:50	3079	134.9
27:50	3074	134.9
26:49 Sterilize	3088	134.8
22:42 Heat-up	76	71.0
14:43 3. Vacuum pulse	1801	116.2



Case #4

$T1 < 134.2^{\circ}\text{C}$ ($T1 = 134.1^{\circ}\text{C}$)

F0 value	129.1min
Time Drain above ster. temp.	5:00m:5
Max. sterilize temperature	134.9°C
Min. sterilize temperature	134.1°C

More



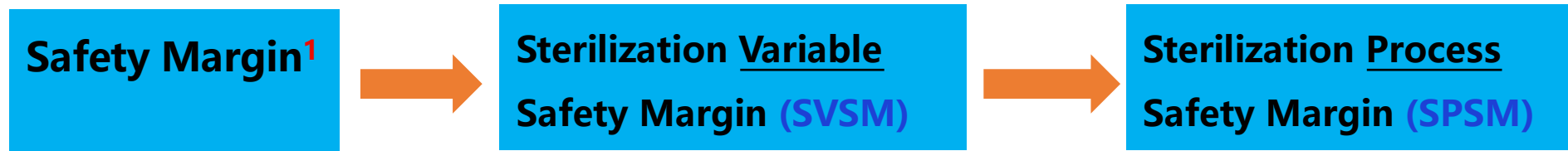
Methods Optimization 1 - B

Introduce 2 more parameters of sterilization phase into the preventive intervention criteria

	W	X	Y	Z	AA	AB	AC	AD	AE	AF	AG	AH
	P1对应的 理论蒸汽 温度	P2对应的 理论蒸汽 温度		T1/T2/两 个理论温 度值的 最小值 (同一时刻)	T1/T2/两 个理论温 度值的 最小值 (同一时刻)	同一时刻 的温差 (C)	温度波动 范围 (C)	实际灭菌 时间 (S)	灭菌温度 范围的裕 量 (0C— 3C)	温度均匀 性安全裕 量 (2C)	灭菌时间 安全裕量 (180S)	灭菌时间 安全裕量 (180S)
8	T3	T4										
9	134.7	134.5		134.4	134.7	0.3						
10	134.6	134.7		134.6	135.1	0.5						
11	134.6	134.7		134.6	135.1	0.4						
12	134.6	134.7		134.6	135.1	0.5						
13	134.6	134.7		134.6	135.1	0.5						
14	134.6	134.7		134.6	135.1	0.5						
15	134.6	134.7		134.6	135.1	0.5						
16	134.6	134.7		134.6	135.1	0.5						
17	134.6	134.7		134.6	135.1	0.5						
18	134.6	134.7		134.6	135.1	0.5						
19	134.6	134.7		134.6	135.1	0.5						
20	134.6	134.7		134.6	135.1	0.5						
21	134.6	134.7		134.6	135.1	0.5						
22	134.6	134.7		134.6	135.1	0.5						
23	134.6	134.7		134.6	135.1	0.5						
24	134.6	134.7		134.6	135.1	0.5						
25	134.6	134.7		134.6	135.1	0.5						
26	134.6	134.7		134.6	135.1	0.5						
27	134.6	134.7		134.6	135.1	0.5						
28	134.6	134.7		134.6	135.1	0.5						
29	134.6	134.7		134.6	135.1	0.5						
30	134.6	134.7		134.6	135.1	0.5						
31	134.6	134.7		134.6	135.1	0.5						
32	134.6	134.7		134.6	135.1	0.5						
33	134.6	134.7		134.6	135.1	0.5						
34	134.6	134.7		134.6	135.1	0.5						
35	134.6	134.7		134.6	135.1	0.5						
36	134.6	134.7		134.6	135.1	0.5						
37	134.6	134.7		134.6	135.1	0.5						
38	134.6	134.7		134.6	135.1	0.5						
39	134.6	134.7		134.6	135.1	0.5						
40	134.6	134.7		134.6	135.1	0.5						
41	134.6	134.7		134.6	135.1	0.5						
42	134.6	134.7		134.6	135.1	0.5						
43	134.6	134.7		134.6	135.1	0.5						
44	134.6	134.7		134.6	135.1	0.5						
45	134.6	134.7		134.6	135.1	0.5						
46	134.6	134.7		134.6	135.1	0.5						
47	134.6	134.7		134.6	135.1	0.5						
48	134.6	134.7		134.6	135.1	0.5						
49	134.6	134.7		134.6	135.1	0.5						
50	134.6	134.7		134.6	135.1	0.5						
51	134.6	134.7		134.6	135.1	0.5						
52	134.6	134.7		134.6	135.1	0.5						
53	134.6	134.7		134.6	135.1	0.5						
54	134.6	134.7		134.6	135.1	0.5						
55	134.6	134.7		134.6	135.1	0.5						
56	134.6	134.7		134.6	135.1	0.5						
57	134.6	134.7		134.6	135.1	0.5						
58	134.6	134.7		134.6	135.1	0.5						
59	134.6	134.7		134.6	135.1	0.5						
60	134.6	134.7		134.6	135.1	0.5						
61	134.6	134.7		134.6	135.1	0.5						
62	134.6	134.7		134.6	135.1	0.5						
63	134.6	134.7		134.6	135.1	0.5						
64	134.6	134.7		134.6	135.1	0.5						
65	134.6	134.7		134.6	135.1	0.5						
66	134.6	134.7		134.6	135.1	0.5						
67	134.6	134.7		134.6	135.1	0.5						
68	134.6	134.7		134.6	135.1	0.5						
69	134.6	134.7		134.6	135.1	0.5						
70	134.6	134.7		134.6	135.1	0.5						
71	134.6	134.7		134.6	135.1	0.5						
72	134.6	134.7		134.6	135.1	0.5						
73	134.6	134.7		134.6	135.1	0.5						
74	134.6	134.7		134.6	135.1	0.5						
75	134.6	134.7		134.6	135.1	0.5						
76	134.6	134.7		134.6	135.1	0.5						
77	134.6	134.7		134.6	135.1	0.5						
78	134.6	134.7		134.6	135.1	0.5						
79	134.6	134.7		134.6	135.1	0.5						
80	134.6	134.7		134.6	135.1	0.5						
81	134.6	134.7		134.6	135.1	0.5						
82	134.6	134.7		134.6	135.1	0.5						
83	134.6	134.7		134.6	135.1	0.5						
84	134.6	134.7		134.6	135.1	0.5						
85	134.6	134.7		134.6	135.1	0.5						
86	134.6	134.7		134.6	135.1	0.5						
87	134.6	134.7		134.6	135.1	0.5						
88	134.6	134.7		134.6	135.1	0.5						
89	134.6	134.7		134.6	135.1	0.5						
90	134.6	134.7		134.6	135.1	0.5						
91	134.6	134.7		134.6	135.1	0.5						
92	134.6	134.7		134.6	135.1	0.5						
93	134.6	134.7		134.6	135.1	0.5						
94	134.6	134.7		134.6	135.1	0.5						
95	134.6	134.7		134.6	135.1	0.5						
96	134.6	134.7		134.6	135.1	0.5						
97	134.6	134.7		134.6	135.1	0.5						
98	134.6	134.7		134.6	135.1	0.5						
99	134.6	134.7		134.6	135.1	0.5						
100	134.6	134.7		134.6	135.1	0.5						
101	134.6	134.7		134.6	135.1	0.5						
102	134.6	134.7		134.6	135.1	0.5						
103	134.6	134.7		134.6	135.1	0.5						
104	134.6	134.7		134.6	135.1	0.5						
105	134.6	134.7		134.6	135.1	0.5						
106	134.6	134.7		134.6	135.1	0.5						
107	134.6	134.7		134.6	135.1	0.5						
108	134.6	134.7		134.6	135.1	0.5						
109	134.6	134.7		134.6	135.1	0.5						
110	134.6	134.7		134.6	135.1	0.5						
111	134.6	134.7		134.6	135.1	0.5						
112	134.6	134.7		134.6	135.1	0.5						
113	134.6	134.7		134.6	135.1	0.5						
114	134.6	134.7		134.6	135.1	0.5						
115	134.6	134.7		134.6	135.1	0.5						
116	134.6	134.7		134.6	135.1	0.5						
117	134.6	134.7		134.6	135.1	0.5						
118	134.6	134.7		134.6	135.1	0.5						
119	134.6	134.7		134.6	135.1	0.5						
120	134.6	134.7		134.6	135.1	0.5						
121	134.6	134.7		134.6	135.1	0.5						
122	134.6	134.7		134.6	135.1	0.5						
123	134.6	134.7		134.6	135.1	0.5						
124	134.6	134.7		134.6	135.1	0.5						
125	134.6	134.7		134.6	135.1	0.5						
126	134.6	134.7		134.6	135.1	0.5						
127	134.6	134.7		134.6	135.1	0.5						
128	134.6	134.7		134.6	135.1	0.5						
129	134.6	134.7		134.6	135.1	0.5						
130	134.6	134.7		134.6	135.1	0.5						
131	134.6	134.7		134.6	135.1	0.5						
132	134.6	134.7		134.6	135.1	0.5						
133	134.6	134.7		134.6	135.1	0.5						
134	134.6	134.7		134.6	135.1	0.5						
135	134.6	134.7		134.6	135.1	0.5						
136	134.6	134.7		134.6	135.1	0.5						
137	134.6	134.7		134.6	135.1	0.5						
138	134.6	134.7		134.6	135.1	0.5						
139	134.6	134.7		134.6	135.1	0.5						
140	134.6	134.7		134.6	135.1	0.5						
141	134.6	134.7		134.6	135.1	0.5						
142	134.6	134.7		134.6	135.1	0.5						
143	134.6	134.7		134.6	135.1	0.5						
144	134.6	134.7		134.6	135.1	0.5						
145	134.6	134.7		134.6	135.1	0.5						
146	134.6	134.7		134.6	135.1	0.5						

- Introduce T3 and T4
- Evaluate T3,T4 and T1,T2 all together against EN285
- Define the moment when sterilization phase **starts**: $T1, T2, T3, T4 \text{ all } \geq 134^{\circ}\text{C}$
- Define the moment when sterilization phase **ends**: Any of $T1, T2, T3, T4 < 134$

Methods Optimization 2 - C



- **SVSM% = ABS (Target Value – Measured value) / Target value**

- ① Sterilization Temperature Band SVSM% = $(3^{\circ}\text{C} - \text{Measured Sterilization Temperature Band}) / 3^{\circ}\text{C} \times 100\%$
- ② Holding Time SVSM% = $(\text{Measured Holding Time} - 180\text{s}) / 180\text{s} \times 100\%$
- ③ Sterilization Temperature Deviation SVSM % = $(2^{\circ}\text{C} - \text{Sterilization Temperature Deviation}) / 2^{\circ}\text{C} \times 100\%$

- **SPSM% = Min (all above 3 SVSM%)**

¹ Yao Jinguo, Analysis of Safety Margins of Reactors in Tianjiawan Nuclear Power Plant, Reactor Thermal Fluid Dynamics Design and Experimental Research, July 2007


Results & Discussions

- In total 8257 batches have been evaluated

Basic Fact of Study	Control Group	Experiment Group
Number of batches (134°C,5min)	4115	4142
Number of preventive interventions under Risk Prediction Model	N/A	7

Results & Discussions

➤ Qualification of Sterilization Pack

Indicator of Result	Control Group	Experiment Group	Improvement
Number of sterilization packs processed	155664	146183	
Number of unqualified sterilization packs	315	0	
Qualification rate of sterilization packs	99.78%	100%	0.22% 

Results & Discussions

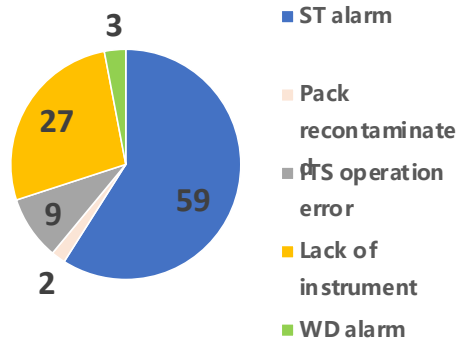
➤ Sterilizer Operation Efficiency

Indicator of Result	Control Group	Experiment Group	Improvement
Operation Time (h) (A)	3925.82	3489.70	
Proactive shutdown due to preventive intervention service(h) (B)	0	3.41	
Passive shutdown due to unexpected alarm and service(h) (C)	339.93	0	
Rate of sterilizer proper operation%* (D)	91.34%	99.90%	8.56% ↑

$$D = (A - B - C) / A \times 100\%$$

Results & Discussions

➤ CSSD Work Efficiency



Breakdown of CSSD delivery delay (Control Group)

Indicator of Result	Control Group	Experiment Group	Improvement
Percentage of delivery delay due to sterilizer unexpected alarm*	59%	0	59% ↓
OT due to sterilizer unexpected alarm (h)	279.50	0	
Percentage of OT due to sterilizer unexpected alarm %	37%	0	37% ↓

*Percentage of delivery delay due to sterilizer alarm% =

$$\frac{\text{Delivery delay cases due to sterilizer alarm}}{\text{Total delivery delay cases}} \times 100\%$$

Results & Discussions

- We invited Dr. Zhang Jinxin and his team from Sun Yat-sen University to analyse two groups' data generated by 4 sterilizers by statistical method



Possible Explanation

- Tolerance of parameter already rather small
- Machine performance quite stable

Indicators Analysed	EN285	P Value
Temperature deviation during sterilization phase (T1,T2,T3,T4)	< 2°C	> 0.05
Temperature fluctuation during sterilization phase	< 3°C	> 0.05
Holding time	> 180s	> 0.05

Results & Discussions

- Improvement of sterilization performance of one sterilizer is observed

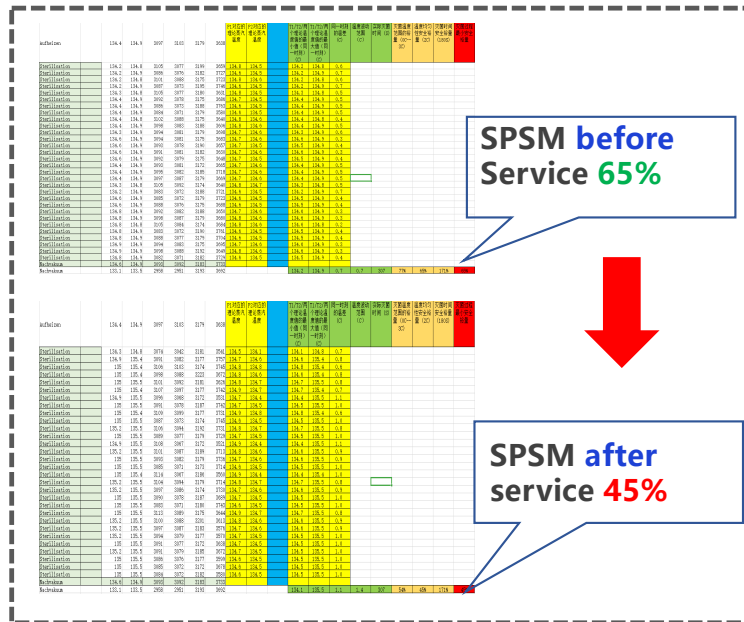
#1 Sterilizer	min T1/T2/T3/T4 °C	max T1/T2/T3/T4 °C	T Deviation °C	Rate of T Deviation (Deviation/2°C)	T Fluctuation °C	Rate of T Fluctuation (Fluctuation/ 3°C)
	Temperature Precision		Temperature Distribution		Temperature Stability	
Without new model (740 batches in total)	134.2	135.2	0.6	29%	1.0	33%
Under new model (685 batches in total)	134.4	135.0	0.5	26%	0.6	21%
Improvement	0.2°C ↑	0.2°C ↓	0.1°C ↓	3% ↓	0.4°C ↓	12% ↓

Results & Discussions

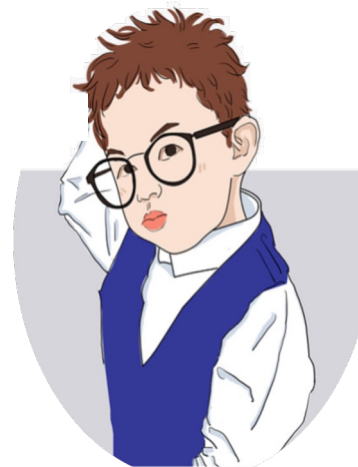


Case #4

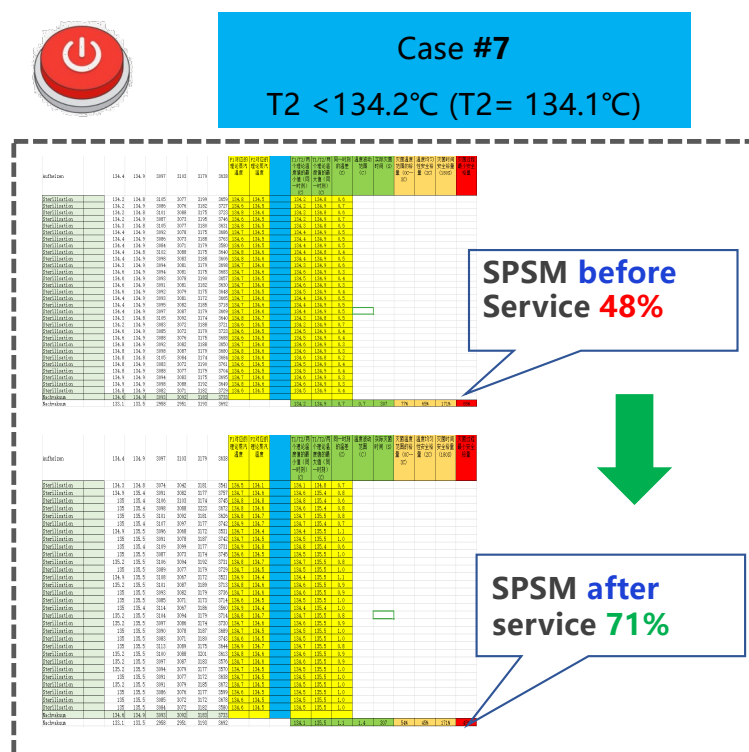
T1 < 134.2°C (T1 = 134.1°C)



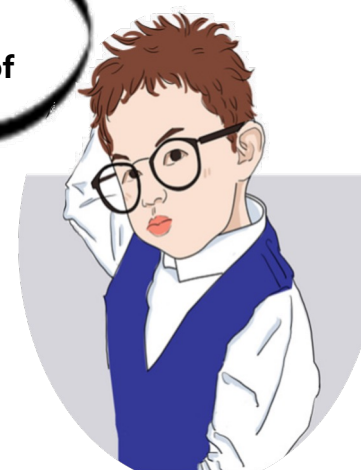
Was the root cause correctly identified and removed by this service intervention?



Results & Discussions



Introducing more process parameters from the batch documentation system could give more precision to the Risk Preventive Model, and at the same time help to create a new quantitative tool for assessing the effect of every service intervention



Conclusion

1

New Management Approach

2

Operate more independently

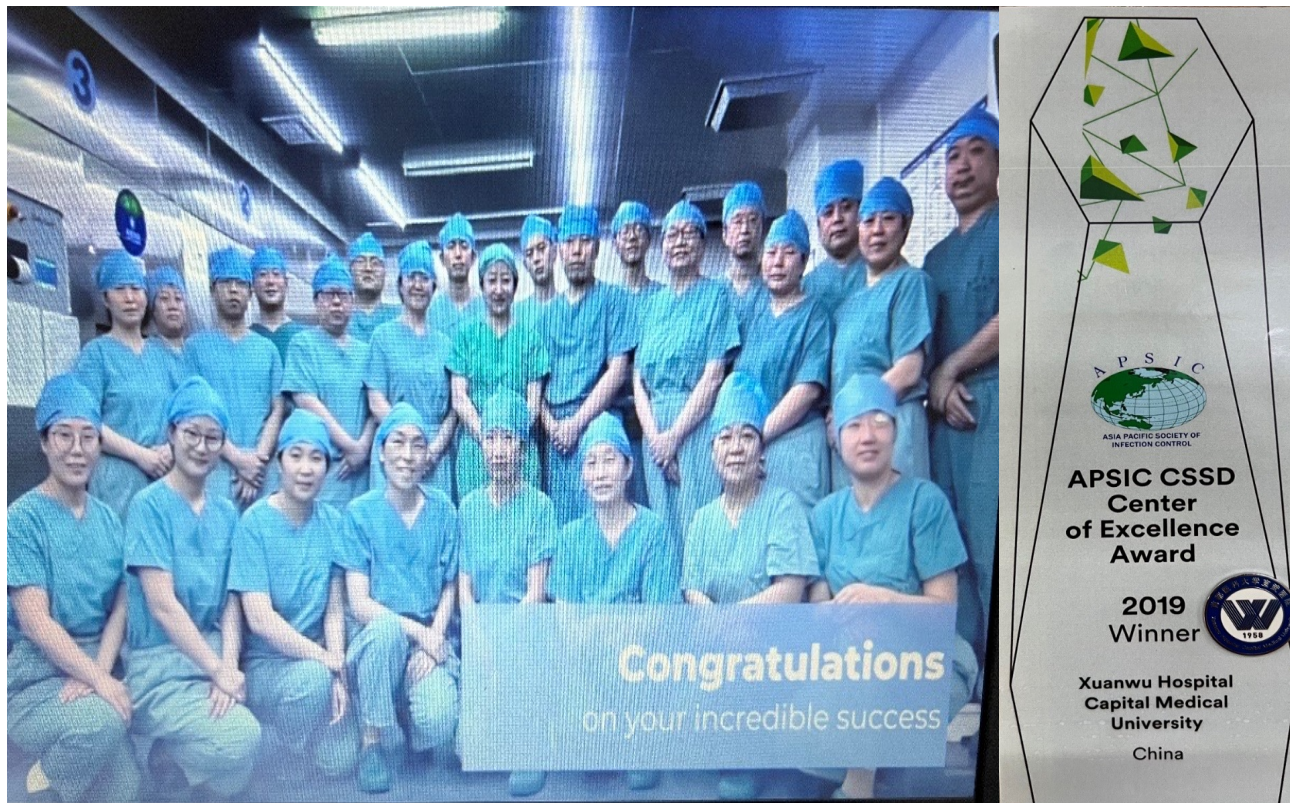
3

Feasibility and Promotion

4

Optimize Continuously - **D**

Acknowledgement



- Ms Liu Ting, Head nurse of OR and CSSD.
(Xuanwu Hospital Of Capital Medical University)
- Dr. Zhang Jinxin and his team
(Sun Yat-Sen University)
- CSSD branch of Chinese Nursing Association

Thanks for your attention!