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

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

backgroud

- 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 equipement!”

backgroud

Sterilizer Unexpected Alarm

- Forced shutdown
- Re- Sterilization
- Delivery delay
- Work overtime
- Waste resources

backgroud

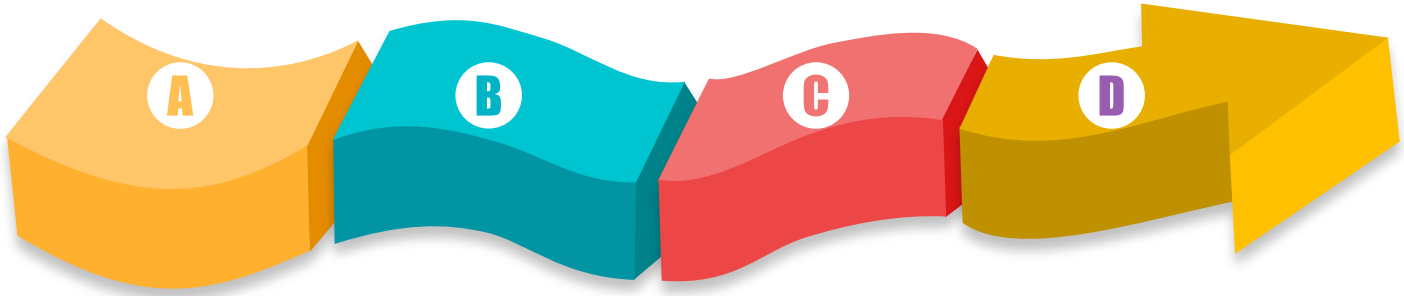
- **24 alarms of sterilizers in total were triggered in 2021.**
- **320 packs had to be re-packed and re-sterilizerd due to those alarms.**

Alarm	Number of Alarm (% of Total)	Resolution
Alarm during Pre-Vac phase	4 (16%)	① Pressure sensor calibration ② Tighten pipings
Alarm during Sterilization phase	10 (42%)	Temperature sensor calibration
Alarm during other 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.

Materrials and Methods - Experiment Group



Batch Report Based

- Define stricter sterilization criteria than machine logic

Batch Documentation System Based

- Take additional 2 Theoritical Temp.into account.

Safety Margin Concept Based

- Inplement Safety Margin concepts for assessment

Finetune Thresholds

- Optimize our criteria by reviewing the statistics

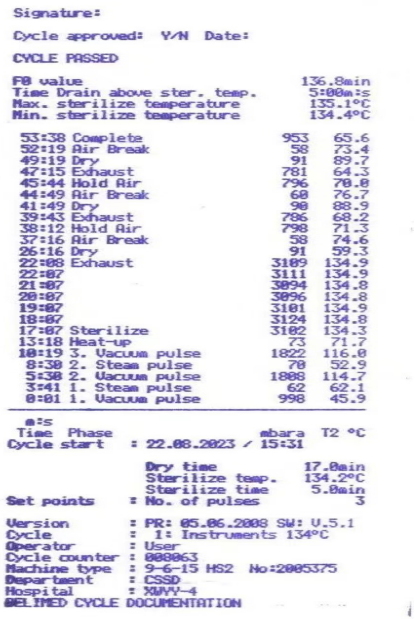
Materrials and Methods - A

- **Object of evaluation**

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

Materrials and Methods - A

Step 1：Read batch report carefully



```
Signature:

Cycle approved:  Y/N  Date:

CYCLE PASSED

F0 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                 60   76.7
 41:49 Dry                       90   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        1888  114.7
  3:41 1. Steam pulse           62   62.1
  0:01 1. Vacuum pulse         998   45.9

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

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

Version       : PR: 05.06.2008 SW: V.5.1
Cycle         :  1: Instruments 134°C
Operator      : User
Cycle counter : 000063
Machine type  : 9-6-15 HS2  No:2005375
Department    : CSSD
Hospital      : XWVV-4
@ELIMED CYCLE DOCUMENTATION
```

Step 2：Understand alarm criteria

Phase	Machine Alarm Criteria
Pre-Vac	Vac Time >**15**min
Steriliza tion	1 Control Temp T1<**134**℃ 2 Deviation between T1&T2 >**1**℃ 3 Deviation between P1&P2>**100**mbar
Other	PLC battery running ≦**24** months

Step 3：Determine preventive intervention criteria

Phase	Preventive Intervention Criteria
Pre-Vac	Vac Time ≧ **8** min
Sterilization	1 T1 or T2 <**134.2**℃ 2 Deviation between T1&T2>**0.6**℃ 3 Deviation between P1&P2>**60**mbar
Other	PLC battery running≦**12** months

Materrials 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	• Evaluate batch report against EN285 • Implement the new preventive intervention criteria
	Only contact service whenever an unexpected alarm is triggered	• 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℃ (T1= 134.1℃)**	**Calibrate T sensor**	**40min**
5		√	751357 (#3)	Deviation T1&T2 >0.6℃	Calibrate T sensor	45min
6		√	752329 (#1)	Deviation T1&T2 >0.6℃	Calibrate T sensor	40min
7		√	752329 (#1)	T2 <134.2℃ (T2= 134.1℃)	Calibrate T sensor	45min

Totally 3h25min

Intermediate Results of Study - A


3-2

Signature:

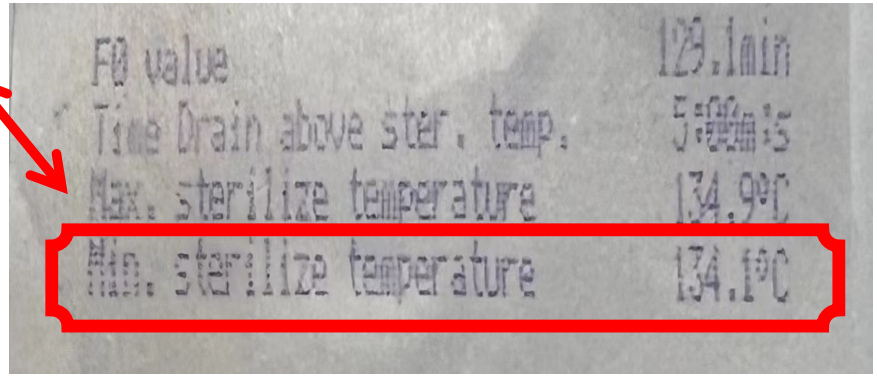
Cycle approved: YN Date:

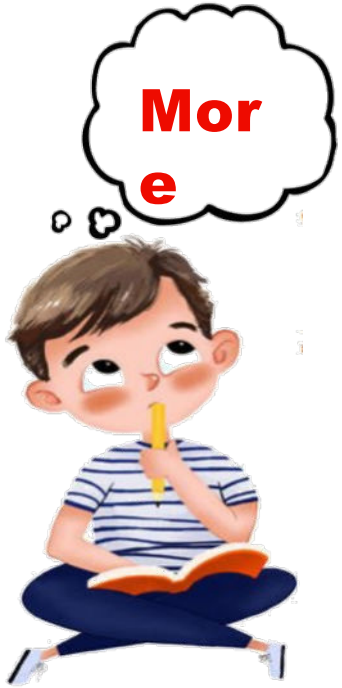
CYCLE PASSED

F0 value		129.1min
Time Drain above ster. temp.		5:00min:s
Max. sterilize temperature		
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
48:43 Dry	95	82.7
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**

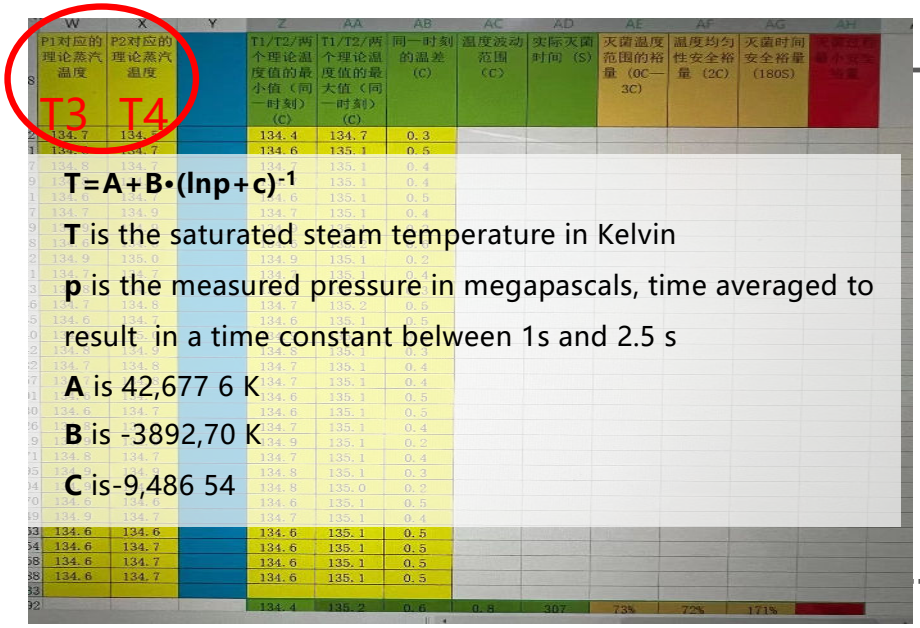
T1 <134.2℃ (T1= 134.1℃)





Methods Optimization 1 - B

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



- Introduce T3 and T4
- Evaluate T3,T4 and T1,T2 all together agaisnt EN285
- Define the moment when sterilization phase **starts**: T1,T2,T3,T4 all ≥ 134℃
- Define the moment when sterilization phase **ends**: Any of T1,T2,T3,T4 < 134

Methods Optimization 2 - C

Safety Margin[1] → **Sterilization Variable Safety Margin (SVSM)** → **Sterilization Process Safety Margin (SPSM)**

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

① Sterilization Temperature Band SVSM% = (3℃ - Measured Sterilization Temperature Band) / 3℃×100%

② Holding Time SVSM% = (Measured Holding Time - 180s)/180s×100%

③ Sterilization Temperature Deviation SVSM % = (2℃- Sterilization Temperature Deviation) / 2℃×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℃,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 sterilizaton packs processed	155664	146183	
Number of unqualified sterilization packs	315	0	
Qualifaction rate of sterilization packs	99.78%	100%	**0.22%** ↑

Results & Discussions

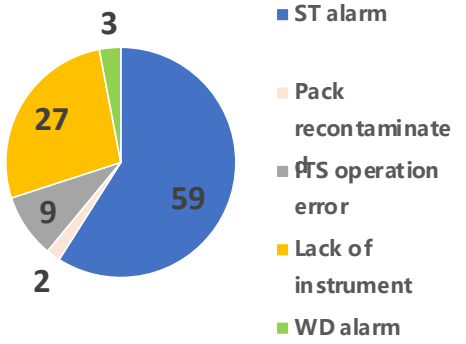
➢ Sterilizer Operation Efficiency

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 x 100%

Results & Discussions

➢ CSSD Work Efficiency



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% ↓

Breakdown of CSSD delivery delay (Control Group)

***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**

中山大學公共衛生學院 SCHOOL OF PUBLIC HEALTH, SUN YAT-SEN UNIVERSITY

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℃	> 0.05
Temperature fluctuation during sterilization phase	< 3℃	> 0.05
Holding time	> 180s	> 0.05

Results & Discussions

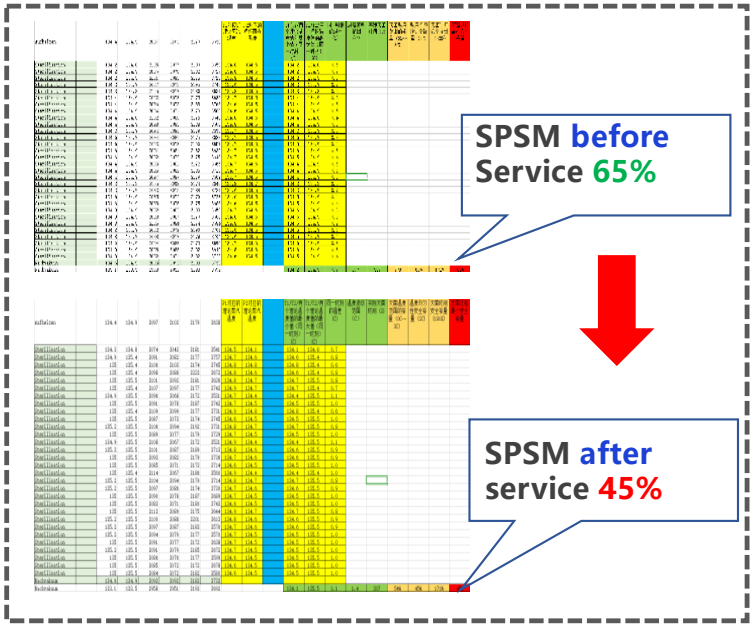
➢ **Improvement of sterilization performance of one sterilizer is observed**

#1 Sterilizer	min T1/T2/T3/T4 ℃	max T1/T2/T3/T4 ℃	T Deviation ℃	Rate of T Deviation (Deviation/2℃)	T Fluctuation ℃	Rate of T Fluctuation (Fluctuation/ 3℃)
	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℃** ↑	**0.2℃** ↓	**0.1℃** ↓	**3%** ↓	**0.4℃** ↓	**12%** ↓

Results & Discussions

Case **#4**

T1 <134.2℃ (T1= 134.1℃)

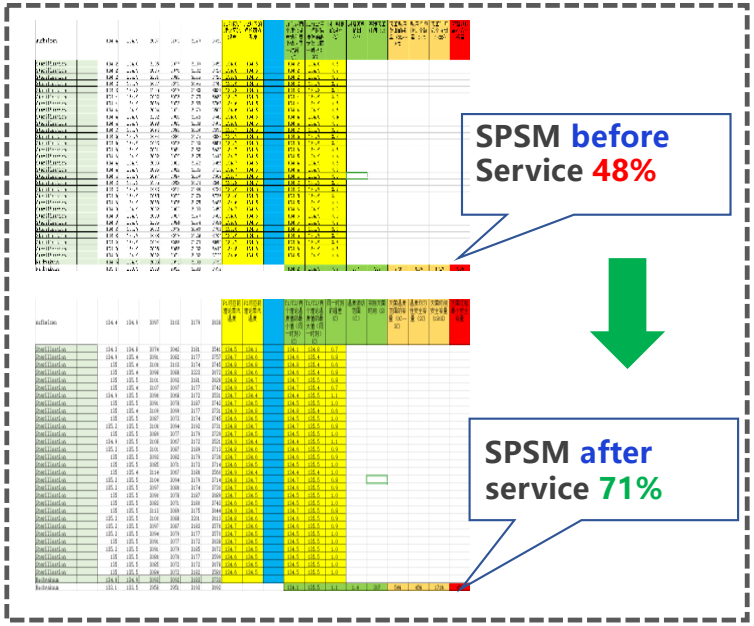


Was the root course correctly identified and removed by this service intervention?

Results & Discussions

Case **#7**

T2 <134.2℃ (T2= 134.1℃)

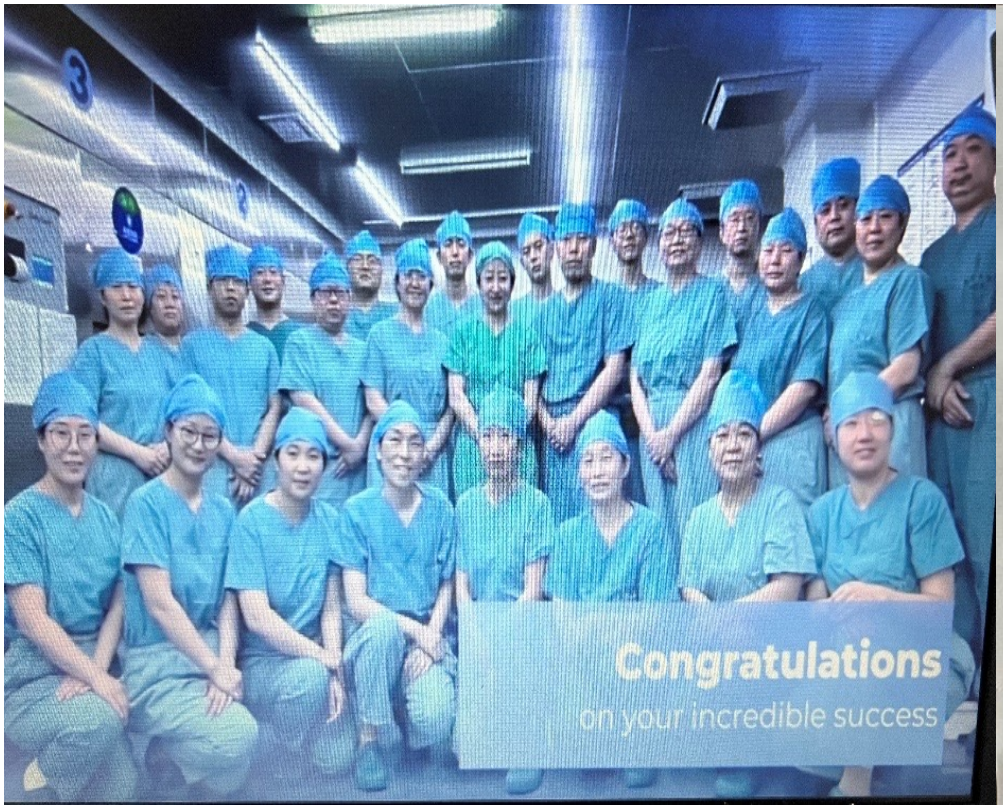


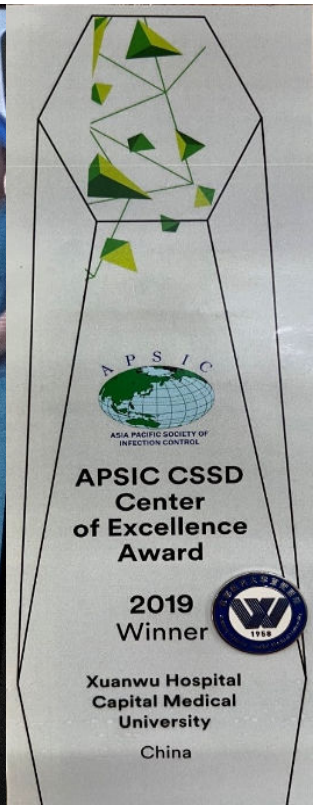
Introducing more process parameters from the batch documentation system could give more precision to the Risk Preventive Model, and at the same time help to create a new quantitative tool for assessing the effect of every service intervention

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!