

The 13th World Forum for Hospital Sterile Supply
Symposium ; Peri-Sterilization Supply Services in Clinical Settings of East Asia region

Sterile Supply Assurance in Clinical Settings of Japan

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The first Conference on Sterilization was held by Japanese Society of Medical Instrumentation (JSMI) in Tokyo University on November 29th 1968 (Chaired by the late Professor S. Jitsukawa). And 6 years later, in 1974 , first volume of “Sterilization and Disinfection” was published.

Hospital Supply Conference started in 1996 (chaired by H. Kobayashi) and since 2000 the conference became to be sponsored by JSMI. At the same time in 2000, certification program of Certified Sterilization Service Technician(2nd grade) was established by certification committee of JSMI (chaired by H. Kobayashi) and Guideline for Sterilization Assurance in Healthcare Setting was published as the educational program. Then certification program of Certified Sterilization Specialist (1st grade) was established in 2002.

These certification programs have contributed to improve the quality of hospital sterile supply service during the last decade in Japan.

1. Guideline for the Sterility Assurance in Healthcare Settings.
2. Certified Sterilization Service Technician (CSST : second grade) & Certified Sterilization Specialist (CSS : first grade) by Japanese Society of Medical Instrumentation.
3. Sterilization Assurance Practices in Clinical Settings.

Guideline for the Sterility Assurance in Healthcare Settings

Guideline for the Sterility Assurance in Healthcare Settings

Issued in 2000

Routine process monitoring



Revised in 2005

Routine process monitoring
+ process validation



Revised in 2010

Guideline for the Sterility Assurance in Healthcare Settings 2010

- General requirements
- Process validation and routine control of washer disinfectors
- Process validation and routine control of steam sterilization
- Process validation and routine control of EO gas sterilization
- Process validation and routine control of hydrogen peroxide gas plasma sterilization
- Process validation and routine control of hydrogen peroxide vapour sterilization
- Chemical indicators
- Biological indicators
- Packaging materials
- Supply and distribution of sterile goods
- Recall of distributed goods
- Chemical sterilant
- Administration of hospital sterilization contractors

Guideline for the Sterility Assurance in Healthcare Settings 2010

Categories of recommendations

Category A : Strongly recommended for
implementation in every facility

Category B : Required for implementation

Category C : Suggested for implementation

Certified Sterilization Service Technician
(CSST: 2nd grade)

&

Certified Sterilization Specialist
(CSS: 1st grade)

by Japanese Society of Medical Instrumentation
(JSMI)

Certification program for CSSD personnel

Certified Sterilization Service Technician

CSST: 2nd grade (since 2000)

- Risk management of sterilizing services
- Improvement of security level for patient care
- Re-evaluation of the importance of sterilization service

Certified Sterilization Specialist

CSS: 1st grade (since 2002)

- Techniques and information for validation and sterility assurance program
- Education for the hospital personnel capable of performing process validation

The number of CSSTs by year

Year	No. certified	Year	No. certified
2000	440	2006	358
2001	286	2007	341
2002	296	2008	333
2003	278	2009	457
2004	289	2010	506
2005	295	2011	505
		Total	4,384

The number of CSSs by year

Year	No. certified
2003	38
2004	24
2005	20
2006	29
2007	16
2008	24
2009	28
2010	30
2011	26
Total	235

Sterilization Assurance Practices in Clinical Settings

Survey on sterility assurance in healthcare settings

Survey: 1998, 2002, 2007, 2012

Subject: The situation of sterility assurance practice in the smaller hospitals

Object: 500 hospitals which have 300 beds or more

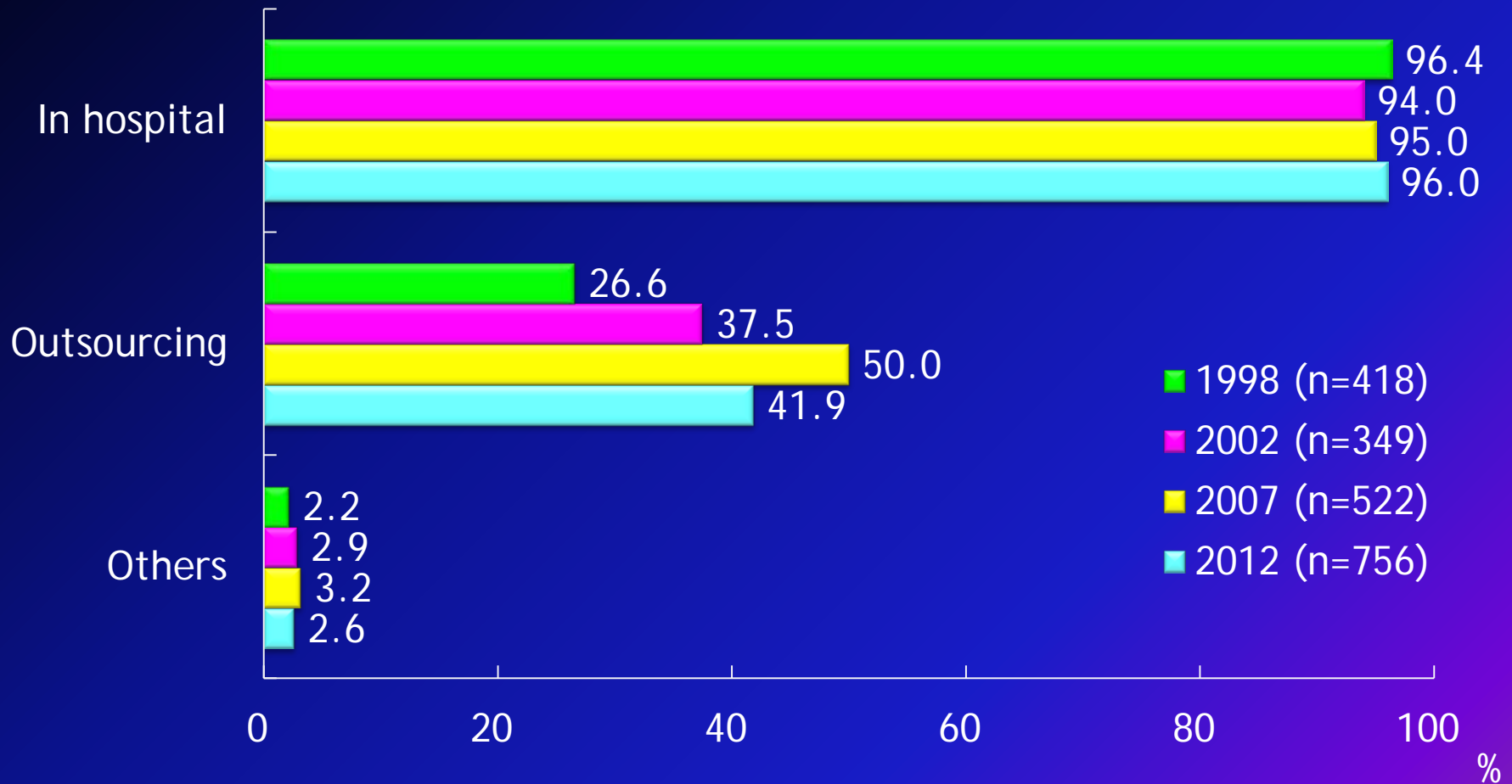
Content: Sterilization methods, # of processing cycle, role in infection control committee, manual for sterilization practice, education program, instruments to be sterilized, packaging system, sterility assurance practice, sterility maintenance policy etc

Number of response

Years	1998	2002	2007	2012
Hospitals which questionnaire was sent to	500 hospitals	500 hospitals	565 hospitals and 1508 CSSs & CSSTs	860 hospitals and 2028 CSSs & CSSTs
No. of hospitals responded	356 (71.2%)	279 (55.8%)	522 (25.2 %*)	764 (26.5%*)

* In some hospitals, several CSSs /CSSTs are working at the same hospital but we received only one questionnaire. So response rate appears to be such lower than actual.

Place of sterilization



Is CSSD Manager a member of ICC

ICC: Infection Control Committee

	YES	NO
1998 (n=416)	57.0 %	43.0 %
2002 (n=351)	54.5 %	45.6 %
2007 (n=510)	67.5 %	32.5 %
2012 (n=708)	75.4 %	28.5 %

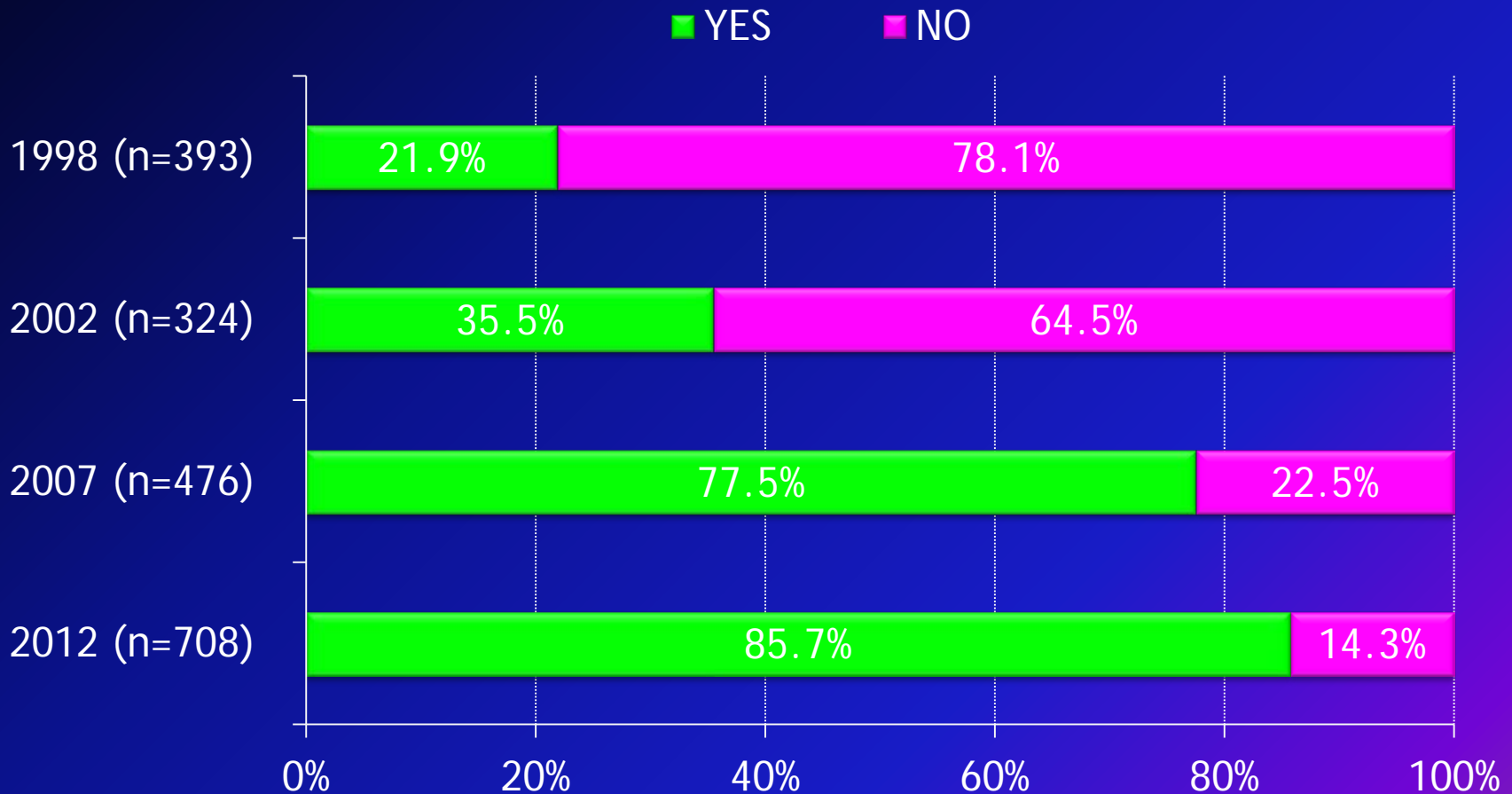
Sterilization packaging material

	Rigid container	Peel pouch	Stainless pot*
1998 (n=419)	61.1 %	46.3 %	87.6 %
2002 (n=354)	71.8 %	98.0 %	65.8 %
2007 (n=520)	68.8 %	99.0 %	54.4 %
2012 (n=563)	74.3 %	99.2 %	41.8 %

* Stainless traditional containers with openable/closable windows which are more easily compromised than rigid containers



Do you routinely perform Bowie-Dick test?



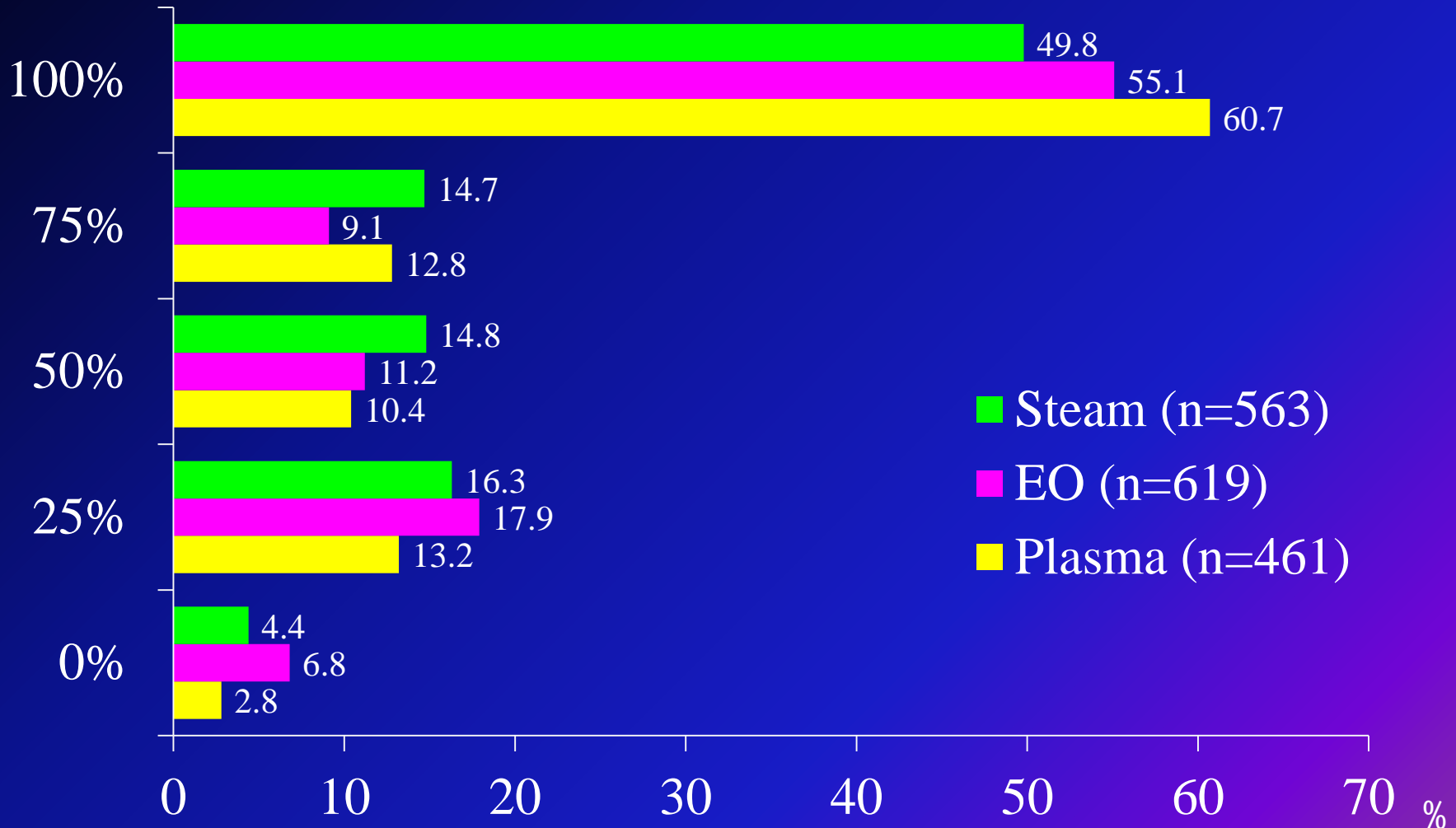
How often do you perform BD test?

	Daily	Daily > > Weekly	Weekly	Less than weekly
1998 (n= ---)	--- %	--- %	--- %	--- %
2002 (n= ---)	--- %	--- %	--- %	--- %
2007 (n=369)	30.1 %	--- %	56.6 %	13.3 %
2012 (n=563)	56.7 %	4.6 %	34.5 %	4.3 %

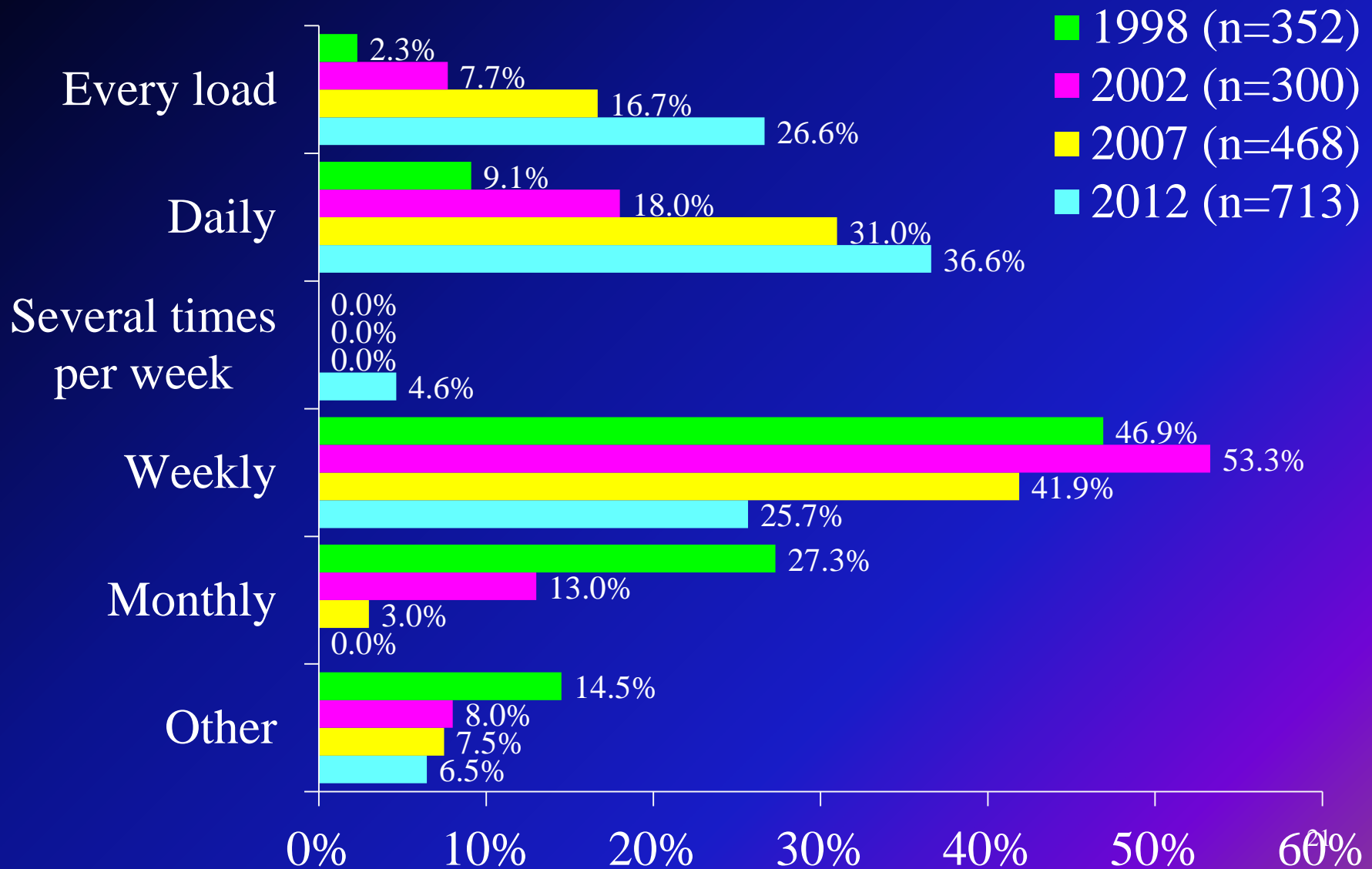
Current Japanese guideline recommendation:

To perform daily as much as you can (Preferably daily)

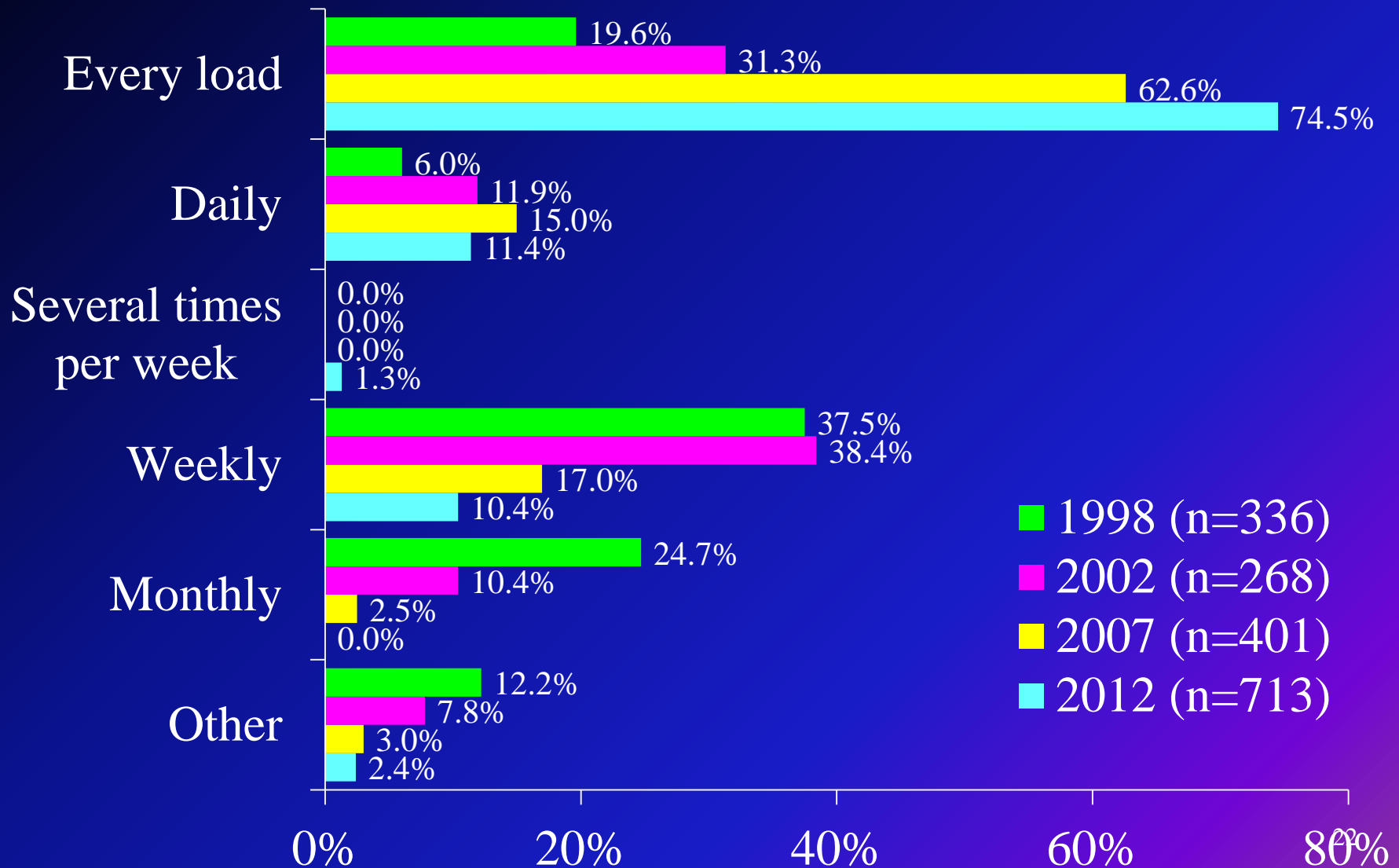
Chemical monitoring (Internal CI) for sterilization processes (2012)



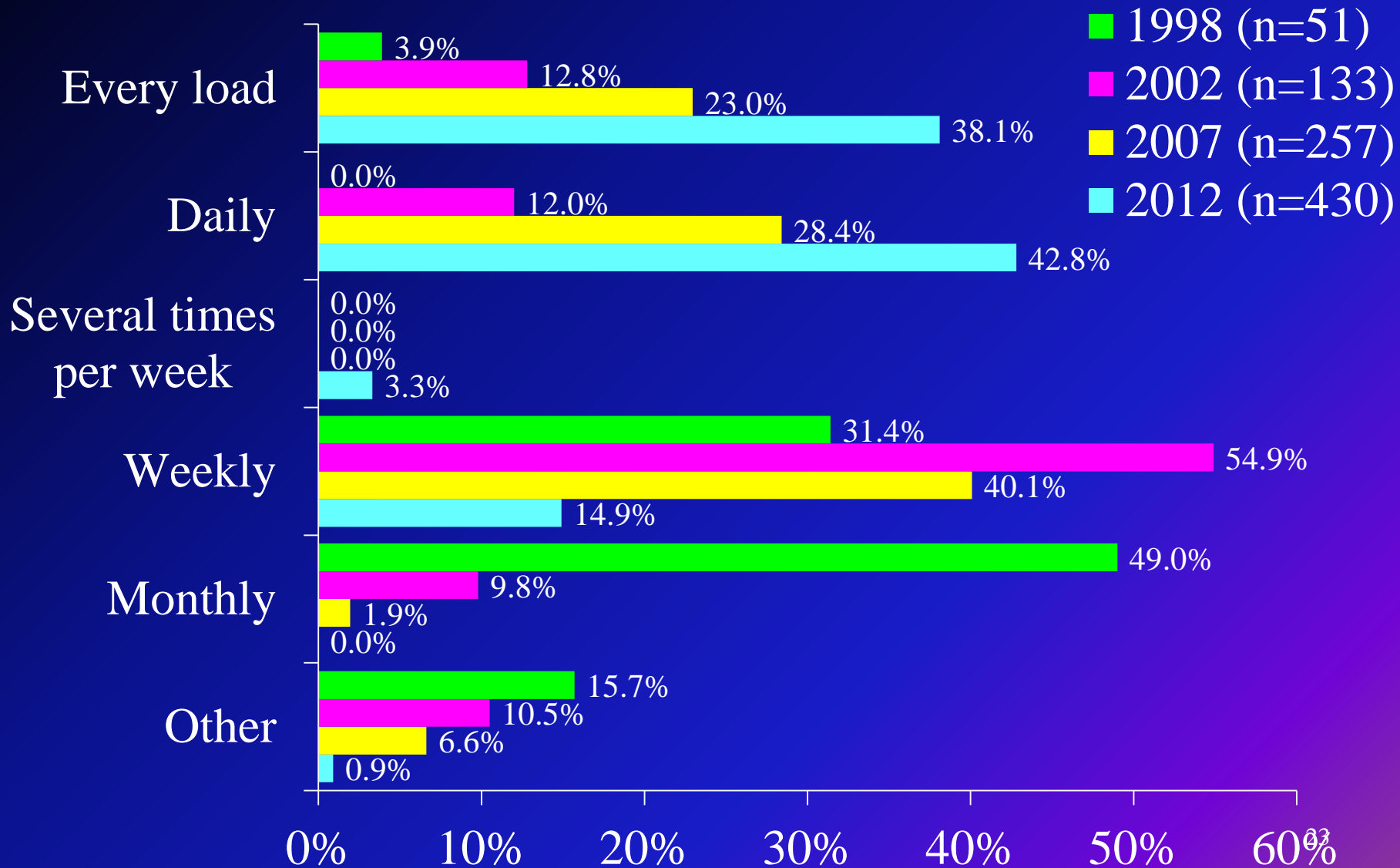
Biological monitoring frequency for Steam sterilization process



Biological monitoring frequency for EO sterilization process



Biological monitoring frequency for Plasma sterilization process



Sterilization process validation

	# of response
Already implemented	207 (44.7%)
Planning to implement	141 (30.5%)
Not planning to implement	47 (10.2%)
Not sure	68 (14.7%)

3rd survey on sterilization assurance
practices in Japanese hospitals 2007

Survey on sterility assurance in healthcare settings

Survey: 2007

Subject: In 2007, a questionnaire was sent to Japanese hospitals with over 500 beds or which certified sterilisation technicians were belonging to. 456 hospitals replied and 207 (45.5%) had implemented sterilization process validation. Additional questionnaire was prepared to investigate the details of the practices of sterilization process validation recommended in JSMI guideline published in 2005 and its responsibility. The questionnaire was sent to those 207 hospitals.

Object: 207 hospitals which have 300 beds or more

Content: Validation item of Installation Qualification
Validation item of Operational Qualification
Validation item of Performance Qualification

Sterilization process validation survey result

The number of hospital responded is 79 (38.2%)

	IQ	OQ	PQ
Steam	72.6~98.7%	15.3~95.7%	8.9~70.8%
EOG	77.9~100%	17.2~96.4%	11.5~64.9%
H₂O₂ gas plasma	73.7~91.5%	12.0~83.6%	13.3~58.8%

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Conclusion

- Contributing factors for quality of sterilization practices in Japanese hospitals
 1. The guideline for sterilization and sterilization assurance
 2. Certification program for CSSD personnel

Thank you very much
for your kind attention