CC - 2603

CERTIFICATE OF CALIBRATION

Certificate Number : TBS/CLC-21/0026-23
Date of Issue : 06-08-2021

CALIBRATION LABORATORY

TBS INDIA TELEMATIC AND BIOMEDICAL SERVICES PVT LTD
5th Floor, Arden Fair, Pai Layout, Old Madras Road, Bangalore–560016.
Tel: 080 - 40545050 Fax: 080 – 40545055
Email: ***in.calibration@althea-group.com***, in.info@althea-group.com

CRF No. :	TBS/CRF-21/0021
CRF Date :	22.07.2021
ULR No :	CC260321000000322F

Customer:
M/s. Sri Venkateswara Institute of Medical Sciences,
Alipiri Rd, Sri Padmavati Mahila Visvavidyalayam,
Tirupati, Andhra Pradesh 517507

Date of Calibration : **28.07.2021**
Recommended Cal Due : **28.07.2022**

Unit Under Calibration:

Nomenclature	: Single Channel Micropipette (Fixed)	Location	: Serology
Make	: Fixapette	Model/Range	: F10
Serial Number	: F17673	Equipment ID No	: Nil
Received Date	: 26.07.2021	Condition of Receipt	: Satisfied

Environmental Condition:

Temperature	: 20±2 ° C	Relative Humidity	: 30-70%
Pressure	: 850hpa to1050hpa	β co-efficient	: 9.9*10^-6 / °C

SOP NO : TBS-CSOP-M-04

Traceability of Master Tags:

Tag Name	Tag No	Cert No	Validity	Traceability
MICRO BALANCE	TBS/CLE/0037	TBS/CLC-20/0055-02	24-11-2021	TBS India, Bangalore

REMARKS:

- β co-efficient is the thermal expansion co-efficient.
- Functionality check only carried out.
- Volume Corrected to 27°C.
- Results obtained ■ Satisfactory.
- Statement of Conformity: The Obtained values are within the tolerance limit as per ISO 8655-6.
- Discipline: Mechanical – Volume

Statements:

- Calibration was carried without any impact of Environmental Condition at TBS India Calibration Laboratory.
- Measurement Uncertainty disclosed @ 95.45%
- Accuracy is calculated as per the manufacturer Specification.

Note : The Certificate is issued subjected to conditions stated overleaf (See back of this page).

Calibrated by
VARNISHA D
Calibration Engineer - Lab

Authorized Signatory
BIVLESH
Quality Manager - Lab

We Value Each and Every Measurement

CERTIFICATE OF CALIBRATION

TBS INDIA TELEMATIC AND BIOMEDICAL SERVICES PVT.LTD

Reg. & Corp. office : 5th & 6th Floor, Arden Fair, Opp Benniganahalli Road Flyover,

Pai Layout, Near Tin Factory, Old Madras Road, Bangalore – 560 016

Certificate No : TBS/CLC-21/0026-23 Date of Issue: 06.08.2021

CALIBRATION RESULTS:-

Range	UUC Setting	Standard Reading	Error Observed	Measurement Uncertainty (±)	Remarks
10 µl	10 µl	9.063 mg	-0.937 mg	0.02 ml	Pass
		9.072 mg	-0.928 mg		
		9.078 mg	-0.922 mg		
		9.085 mg	-0.915 mg		
		9.093 mg	-0.907 mg		
	Systematic Error :	-9.218 %	Mean Value :	9.078 mg	
	Random Error :	0.127 %	Standard Deviation :	0.012 mg	
	Volume Delivered:	9.088 µl			

Medium used : Grade 3 Distilled Water.

Error Limit : ± 0.120 µl

UUC is defined Unit Under Calibration

Conclusion: Obtained values are within the Tolerance Limit as per ISO 8655.Hence the pipette is found to be working fine.

*******END OF REPORT*******

Calibrated by:

VARNISHA D
Calibration Engineer - Lab

Authorized Signatory:

BINEESH
Quality Manager - Lab

CC - 2603

CERTIFICATE OF CALIBRATION

Certificate Number : TBS/CLC-21/0026-06
Date of Issue : 06-08-2021

CALIBRATION LABORATORY

TBS INDIA TELEMATIC AND BIOMEDICAL SERVICES PVT LTD
5th Floor, Arden Fair, Pai Layout, Old Madras Road, Bangalore–560016.
Tel: 080 - 40545050 Fax: 080 – 40545055
Email: ***in.calibration@althea-group.com***, in.info@althea-group.com

CRF No. :	TBS/CRF-21/0021
CRF Date :	22.07.2021
ULR No :	CC260321000000305F

Customer:

M/s. Sri Venkateswara Institute of Medical Sciences,
Alipiri Rd, Sri Padmavati Mahila Visvavidyalayam,
Tirupati, Andhra Pradesh 517507

Date of Calibration : **28.07.2021**
Recommended Cal Due : **28.07.2022**

Unit Under Calibration:

Nomenclature	: Single Channel Micropipette (Variable)	Location	: Serology
Make	: Accupipet	Model/Range	: T200
Serial Number	: V22106	Equipment ID No	: Nil
Received Date	: 26.07.2021	Condition of Receipt	: Satisfied

Environmental Condition:

Temperature	: 20±2 ° C	Relative Humidity	: 30-70%
Pressure	: 850hpa to1050hpa	β co-efficient	: 9.9*10^-6 / °C

SOP NO : TBS-CSOP-M-04

Traceability of Master Tags:

Tag Name	Tag No	Cert No	Validity	Traceability
MICRO BALANCE	TBS/CLE/0037	TBS/CLC-20/0055-02	24-11-2021	TBS India, Bangalore

REMARKS:

- β co-efficient is the thermal expansion co-efficient.
- Functionality check only carried out.
- Volume Corrected to 27°C.
- Results obtained ■ Partially Satisfactory.
- Statement of Conformity: The pipette is found to be partially working since the obtained values are exceeding the error limit of ±1.6 µl for the range of 200 µl as per ISO 8655-6.
- Discipline: Mechanical – Volume

Statements:

- Calibration was carried without any impact of Environmental Condition at TBS India Calibration Laboratory.
- Measurement Uncertainty disclosed @ 95.45%
- Accuracy is calculated as per the manufacturer Specification.

Note : The Certificate is issued subjected to conditions stated overleaf (See back of this page).

Calibrated by

VARNISHA D
Calibration Engineer - Lab

Authorized Signatory

BINEESH
Quality Manager - Lab

We Value Each and Every Measurement

CERTIFICATE OF CALIBRATION

TBS INDIA TELEMATIC AND BIOMEDICAL SERVICES PVT.LTD
Reg. & Corp. office : 5th & 6th Floor, Arden Fair, Opp Benniganahalli Road Flyover,
Pai Layout, Near Tin Factory, Old Madras Road, Bangalore – 560 016

Certificate No : TBS/CLC-21/0026-06 Date of Issue: 06.08.2021

CALIBRATION RESULTS:-

Range	UUC Setting	Standard Reading	Error Observed	Measurement Uncertainty (±)	Remarks
20 µl to 200 µl	20 µl	21.034 mg	1.034 mg	0.11 ml	Pass
		21.046 mg	1.046 mg		
		21.052 mg	1.052 mg		
		21.064 mg	1.064 mg		
		21.069 mg	1.069 mg		
	Systematic Error :	5.265 %	Mean Value :	21.053 mg	
	Random Error :	0.067 %	Standard Deviation :	0.014 mg	
	Volume Delivered:	21.076 µl			
	100 µl	100.012 mg	0.012 mg	0.11 ml	Pass
		100.014 mg	0.014 mg		
		100.023 mg	0.023 mg		
		100.026 mg	0.026 mg		
		100.033 mg	0.033 mg		
	Systematic Error :	0.022 %	Mean Value :	100.022 mg	
	Random Error :	0.009 %	Standard Deviation :	0.009 mg	
	Volume Delivered:	100.131 µl			
	200 µl	196.712 mg	-3.288 mg	----- ml	Fail
		196.723 mg	-3.277 mg		
		196.735 mg	-3.265 mg		
		196.743 mg	-3.257 mg		
		196.754 mg	-3.246 mg		
	Systematic Error :	-1.633 %	Mean Value :	196.733 mg	
	Random Error :	0.008 %	Standard Deviation :	0.016 mg	
	Volume Delivered:	196.949 µl			

Medium used : Grade 3 Distilled Water.
Error Limit : ± 1.6 µl
UUC is defined Unit Under Calibration
Conclusion: The pipette is found to be partially working since the obtained values are exceeding the error limit of ±1.6 µl for the range of 200 µl as per ISO 8655-6.

*****END OF REPORT*****

Calibrated by:
VARNISHA D
Calibration Engineer - Lab

Authorized Signatory:
BINEESH
Quality Manager - Lab

CERTIFICATE OF CALIBRATION

Certificate Number : TBS/CLC-21/0026-03
Date of Issue : 06-08-2021

CC - 2603

CALIBRATION LABORATORY

TBS INDIA TELEMATIC AND BIOMEDICAL SERVICES PVT LTD
5th Floor, Arden Fair, Pai Layout, Old Madras Road, Bangalore–560016.
Tel: 080 - 40545050 Fax: 080 – 40545055
Email: ***in.calibration@althea-group.com***, in.info@althea-group.com

CRF No. :	TBS/CRF-21/0021
CRF Date :	22.07.2021
ULR No :	CC260321000000302F

Customer:

M/s. Sri Venkateswara Institute of Medical Sciences,
Alipiri Rd, Sri Padmavati Mahila Visvavidyalayam,
Tirupati, Andhra Pradesh 517507

Date of Calibration : **28.07.2021**
Recommended Cal Due : **28.07.2022**

Unit Under Calibration:

Nomenclature	: Single Channel Micropipette (Fixed)	Location	: Serology
Make	: Thermoscientific	Model/Range	: Finnpipette F3
Serial Number	: HH52352	Equipment ID No	: Nil
Received Date	: 26.07.2021	Condition of Receipt	: Satisfied

Environmental Condition:

Temperature	: 20±2 ° C	Relative Humidity	: 30-70%
Pressure	: 850hpa to1050hpa	β co-efficient	: 9.9*10^-6 / °C

SOP NO : TBS-CSOP-M-04

Traceability of Master Tags:

Tag Name	Tag No	Cert No	Validity	Traceability
MICRO BALANCE	TBS/CLE/0037	TBS/CLC-20/0055-02	24-11-2021	TBS India, Bangalore

REMARKS:

- β co-efficient is the thermal expansion co-efficient.
- Functionality check only carried out.
- Volume Corrected to 27°C.
- Results obtained ■ Satisfactory.
- Statement of Conformity: The Obtained values are within the tolerance limit as per ISO 8655-6.
- Discipline: Mechanical – Volume

Statements:

- Calibration was carried without any impact of Environmental Condition at TBS India Calibration Laboratory.
- Measurement Uncertainty disclosed @ 95.45%
- Accuracy is calculated as per the manufacturer Specification.

Note : The Certificate is issued subjected to conditions stated overleaf (See back of this page).

Calibrated by

VARNISHA D
Calibration Engineer - Lab

Authorized Signatory

BINEESH
Quality Manager - Lab

We Value Each and Every Measurement

CERTIFICATE OF CALIBRATION

TBS INDIA TELEMATIC AND BIOMEDICAL SERVICES PVT.LTD

Reg. & Corp. office : 5th & 6th Floor, Arden Fair, Opp Benniganahalli Road Flyover,

Pai Layout, Near Tin Factory, Old Madras Road, Bangalore – 560 016

Certificate No : TBS/CLC-21/0026-03

Date of Issue: 06.08.2021

CALIBRATION RESULTS:-

Range	UUC Setting	Standard Reading	Error Observed	Measurement Uncertainty (±)	Remarks
100 µl	100 µl	100.214 mg	0.214 mg	0.11 ml	Pass
		100.219 mg	0.219 mg		
		100.223 mg	0.223 mg		
		100.226 mg	0.226 mg		
		100.234 mg	0.234 mg		
	Systematic Error :	0.223 %	Mean Value :	100.223 mg	
	Random Error :	0.008 %	Standard Deviation :	0.008 mg	
	Volume Delivered:	100.333 µl			

Medium used : Grade 3 Distilled Water.

Error Limit : ± 0.8 µl

UUC is defined Unit Under Calibration

Conclusion: Obtained values are within the Tolerance Limit as per ISO 8655.Hence the pipette is found to be working fine.

*******END OF REPORT*******

Calibrated by:

VARNISHA D
Calibration Engineer - Lab

Authorized Signatory:

BINEESH
Quality Manager - Lab

CERTIFICATE OF CALIBRATION

Certificate Number : TBS/CLC-21/0026-01
Date of Issue : 06-08-2021

CC - 2603

CALIBRATION LABORATORY

TBS INDIA TELEMATIC AND BIOMEDICAL SERVICES PVT LTD
5th Floor, Arden Fair, Pai Layout, Old Madras Road, Bangalore-560016.
Tel: 080 - 40545050 Fax: 080 – 40545055
Email: ***in.calibration@althea-group.com***, in.info@althea-group.com

CRF No. :	TBS/CRF-21/0021
CRF Date :	22.07.2021
ULR No :	CC260321000000300F

Customer:
M/s. Sri Venkateswara Institute of Medical Sciences,
Alipiri Rd, Sri Padmavati Mahila Visvavidyalayam,
Tirupati, Andhra Pradesh 517507

Date of Calibration : **28.07.2021**
Recommended Cal Due : **28.07.2022**

Unit Under Calibration:

Nomenclature	: Single Channel Micropipette (Variable)	Location	: Serology
Make	: Thermoscientific	Model/Range	: Finnpipette F2
Serial Number	: RW08097	Equipment ID No	: Nil
Received Date	: 26.07.2021	Condition of Receipt	: Satisfied

Environmental Condition:

Temperature	: 20±2 ° C	Relative Humidity	: 30-70%
Pressure	: 850hpa to1050hpa	β co-efficient	: 9.9*10^-6 / °C

SOP NO : TBS-CSOP-M-04

Traceability of Master Tags:

Tag Name	Tag No	Cert No	Validity	Traceability
MICRO BALANCE	TBS/CLE/0037	TBS/CLC-20/0055-02	24-11-2021	TBS India, Bangalore

REMARKS:

- β co-efficient is the thermal expansion co-efficient.
- Functionality check only carried out.
- Volume Corrected to 27°C.
- Results obtained ■ Satisfactory.
- Statement of Conformity: The Obtained values are within the tolerance limit as per ISO 8655-6.
- Discipline: Mechanical – Volume

Statements:

- Calibration was carried without any impact of Environmental Condition at TBS India Calibration Laboratory.
- Measurement Uncertainty disclosed @ 95.45%
- Accuracy is calculated as per the manufacturer Specification.

Note : The Certificate is issued subjected to conditions stated overleaf (See back of this page).

Calibrated by
VARNISHA D
Calibration Engineer - Lab

Authorized Signatory
BINESH
Quality Manager - Lab

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CERTIFICATE OF CALIBRATION

TBS INDIA TELEMATIC AND BIOMEDICAL SERVICES PVT.LTD
Reg. & Corp. office : 5th & 6th Floor, Arden Fair, Opp Benniganahalli Road Flyover,
Pai Layout, Near Tin Factory, Old Madras Road, Bangalore – 560 016

Certificate No : TBS/CLC-21/0026-01 Date of Issue: 06.08.2021

CALIBRATION RESULTS:-

Range	UUC Setting	Standard Reading	Error Observed	Measurement Uncertainty (±)	Remarks
2 µl to 20 µl	2 µl	2.163 mg	0.163 mg	0.02 ml	Pass
		2.168 mg	0.168 mg		
		2.175 mg	0.175 mg		
		2.179 mg	0.179 mg		
		2.183 mg	0.183 mg		
	Systematic Error :	8.680 %	Mean Value :	2.174 mg	
	Random Error :	0.373 %	Standard Deviation :	0.008 mg	
	Volume Delivered:	2.176 µl			
	10 µl	10.053 mg	0.053 mg	0.11 ml	Pass
		10.062 mg	0.062 mg		
		10.068 mg	0.068 mg		
		10.075 mg	0.075 mg		
		10.081 mg	0.081 mg		
	Systematic Error :	0.678 %	Mean Value :	10.068 mg	
	Random Error :	0.109 %	Standard Deviation :	0.011 mg	
	Volume Delivered:	10.079 µl			
	20 µl	19.932 mg	-0.068 mg	0.11 ml	Pass
		19.936 mg	-0.064 mg		
		19.941 mg	-0.059 mg		
		19.945 mg	-0.055 mg		
		19.949 mg	-0.051 mg		
	Systematic Error :	-0.297 %	Mean Value :	19.941 mg	
	Random Error :	0.034 %	Standard Deviation :	0.007 mg	
	Volume Delivered:	19.962 µl			

Medium used : Grade 3 Distilled Water.
Error Limit : ± 0.20 µl
UUC is defined Unit Under Calibration

Conclusion: Obtained values are within the Tolerance Limit as per ISO 8655.Hence the pipette is found to be working fine.

*******END OF REPORT*******

Calibrated by:
VARNISHA D
Calibration Engineer - Lab

Authorized Signatory:
BINDESH
Quality Manager - Lab

L-J Table

File No.: 4 Lot No.: BC210113 Exp. Date: 10-05-2021

QC Mode: Whole Blood Level: High Editor: Service Engineer

Current Page/Total Pages: 2 / 3 Date Range: 30-03-2021 — 19-04-2021 Print Time: 08-05-2021 15:17:31

QC ID:

Table

	Target	Limits	7	8	9	10	11	12
Date	/	/	06-04-2021	07-04-2021	08-04-2021	09-04-2021	10-04-2021	12-04-2021
Time	/	/	08:45:52	08:46:11	08:44:01	08:51:24	08:39:54	08:30:29
Operator	/	/	svims	svims	svims	svims	svims	svims
WBC	17.20	2.50	17.77	18.64	18.37	18.17	18.11	18.97
RBC	4.89	0.30	5.14	H 5.21	H 5.23	5.13	5.14	H 5.28
HGB	15.9	0.8	15.9	16.2	16.0	15.9	16.2	16.4
PLT	475	60	509	H 537	501	518	528	491
Neu%	66.0	10.0	72.0	72.9	72.6	71.8	73.4	71.3
Lym%	18.9	8.0	15.7	14.9	17.9	18.0	17.3	17.3
Mon%	4.5	4.0	5.7	5.9	5.5	6.2	5.9	6.4
Eos%	10.6	8.0	6.6	6.3	4.0	4.0	5.4	5.0
Bas%	78.8	10.0	76.1	75.8	75.0	74.6	74.9	75.1
Neu#	11.35	2.55	12.79	13.59	13.34	13.05	13.28	13.53
Lym#	3.25	1.38	2.79	2.77	3.27	3.27	3.13	3.27
Mon#	0.77	0.69	1.01	1.10	1.02	1.31	0.71	1.22
Eos#	1.82	1.38	1.18	1.18	0.74	0.74	0.99	0.95
Bas#	13.55	1.72	13.53	14.13	13.77	13.55	13.57	14.25
HCT	51.6	2.4	53.2	H 54.1	H 54.4	53.5	53.7	H 54.7
MCV	105.5	5.0	103.4	103.7	103.9	104.4	104.6	103.7
MCH	32.5	2.5	30.9	31.1	30.6	31.0	31.4	31.0
MCHC	30.8	3.0	29.9	30.0	29.4	29.7	30.1	29.9
RDW-CV			20.1	19.8	20.4	20.2	20.3	20.8
RDW-SD			87.9	86.9	89.9	88.9	89.5	90.9
MPV	9.6	3.0	8.1	8.1	7.9	8.1	8.3	7.6
PDW	16.4	3.0	16.8	16.9	16.6	16.9	17.0	16.4
PCT	0.456	0.200	0.410	0.435	0.396	0.420	0.456	0.374

L-J Table

File No.: 4
Lot No.: BC21011b
Exp. Date: 10-05-2021
QC Mode: Whole Blood
Level: High
Editor: Service Engineer
Current Page/Total Pages: 2 / 3
Date Range: 30-03-2021 — 19-04-2021
Print Time: 08-05-2021 15:47:31

QC ID:

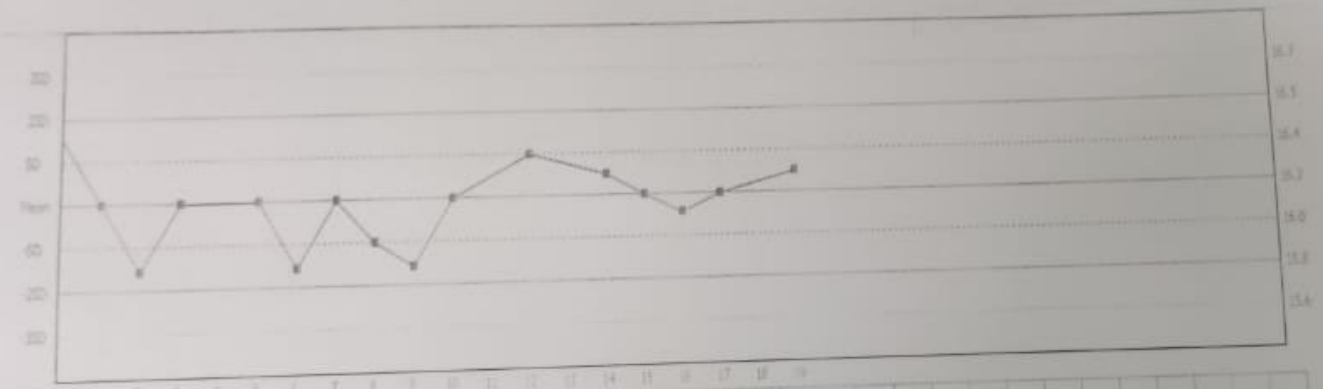
Table

	Target	Limits	7	8	9	10	11	12
Date			06-04-2021	07-04-2021	08-04-2021	09-04-2021	10-04-2021	12-04-2021
Time			08:45:52	08:46:11	08:44:01	08:51:24	08:39:54	08:30:29
Operator			svims	svims	svims	svims	svims	svims
WBC	17.20	2.50	17.77	18.64	18.37	18.17	18.11	18.97
RBC	4.89	0.30	5.14	H 5.21	H 5.23	5.13	5.14	H 5.28
HGB	15.9	0.8	15.9	16.2	16.0	15.9	16.2	16.4
PLT	475	60	509	H 537	501	518	528	491
Neu%	66.0	10.0	72.0	72.9	72.6	71.8	73.4	71.3
Lym%	18.9	8.0	15.7	14.9	17.9	18.0	17.3	17.3
Mon%	4.5	4.0	5.7	5.9	5.5	6.2	3.9	6.4
Eos%	10.6	8.0	6.6	6.3	4.0	4.0	5.4	5.0
Bas%	78.8	10.0	76.1	75.8	75.0	74.6	74.9	75.1
Neu#	11.35	2.55	12.79	13.59	13.34	13.05	13.28	13.53
Lym#	3.25	1.38	2.79	2.77	3.27	3.27	3.13	3.27
Mon#	0.77	0.69	1.01	1.10	1.02	1.18	0.71	1.22
Eos#	1.82	1.38	1.18	1.18	0.74	0.74	0.99	0.95
Bas#	13.55	1.72	13.53	14.13	13.77	13.55	13.57	14.25
HCT	51.6	2.4	53.2	H 54.1	H 54.4	53.5	53.7	H 54.7
MCV	105.5	5.0	103.4	103.7	103.9	104.4	104.6	103.7
MCH	32.5	2.5	30.9	31.1	30.6	31.0	31.4	31.0
MCHC	30.8	3.0	29.9	30.0	29.4	29.7	30.1	29.9
RDW-CV			20.1	19.8	20.4	20.2	20.3	20.8
RDW-SD			87.9	86.9	89.9	88.9	89.5	90.9
MPV	9.6	3.0	8.1	8.1	7.9	8.1	8.3	7.6
PDW	16.4	3.0	16.8	16.9	16.6	16.9	17.0	16.4
PCT	0.456	0.200	0.410	0.435	0.396	0.420	0.436	0.374

Single Para. QC Graph

File No.: 4 Lot No.: BC2101D Exp. Date: 10-05-2021 QC Mode: Whole Blood Level: High

QC ID: Parameter: HGB Date Range: 30-03-2021 — 19-04-2021 Current Page/All Data: 15/17 Print Time: 08-05-2021 13:13:14



2021-4	1	2	3	4	5	7	8	9	10	11	12	13	14	15	16	17	18	19
Result	16.1	15.8	16.2		16.1	15.9	16.2	16.0	15.9	16.1		16.4		16.3	16.3	16.1	16.2	
Operator	[illegible]	[illegible]	[illegible]		[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]		[illegible]		[illegible]	[illegible]	[illegible]	[illegible]	

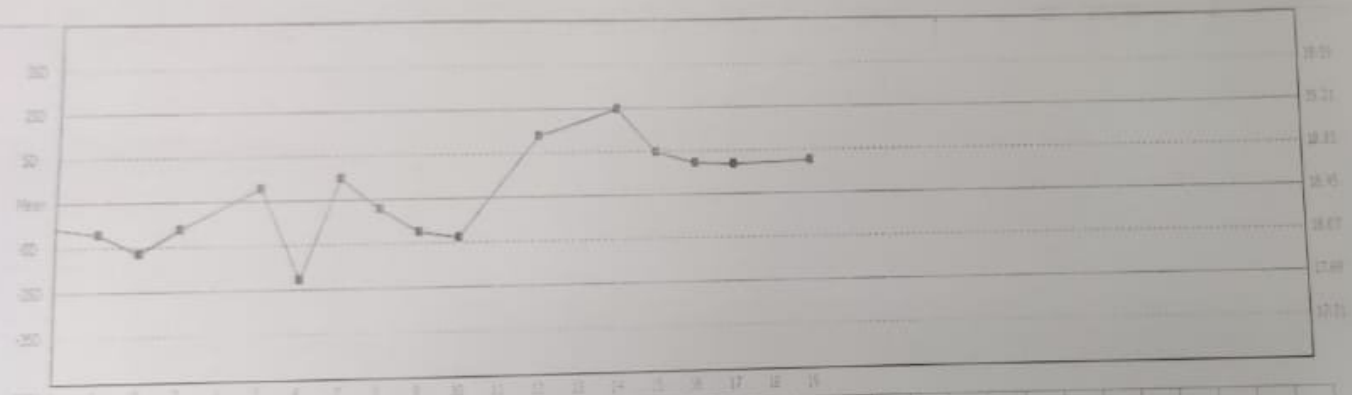
Valid Counts: 17 Mean: 16.2 SD: 0.2

Evaluated by: system

Single Para. QC Graph

File No: 4 Lot No : BC2101N Exp. Date: 10-05-2021 QC Mode: Whole Blood Level: High

QC ID: Parameter: WBC Date Range: 10-03-2021 — 19-04-2021 Current Page/All Data 13/17 Print Time: 08-05-2021 15:10:24



2021-4	1	4	7	8	1	4	7	8	9	10	11	12	13	14	15	16	17	18	19
Result	18.26	18.03	18.22		18.36	17.77	18.44	18.37	18.17	18.13		18.47		18.26	18.02	17.72	18.71		18.37
Operator	ssvms	ssvms	ssvms		ssvms	ssvms	ssvms	ssvms	ssvms	ssvms		ssvms		ssvms	ssvms	ssvms	ssvms		ssvms

Valid Counts: 17 Mean: 18.45 SD: 0.38

Evaluated by: ssvms

Haematology — Quality Control

62

29/4/21

Analyser	Hb	pcv	RBC	TC	mcv	mch	PLC
old value	12.8	42.9	4.47	4600	96	28	2.38
BC 5300 I	12.5	43.1	4.70	4700	92	27	2.63
BC 5300 II	12.8	41.1	4.88	4500	84	26	2.66
old value	16.0	46.8	5.58	14200	84	29	2.37
BC 5300 I	15.8	50.4	5.56	15400	91	28	2.26
BC 5300 II	16.1	49.5	5.25	14800	94	31	2.19

30/4/21

old value	11.6	39.5	4.47	6400	82	26	2.73
BC 5300 I	11.6	39.5	4.47	6500	88	26	2.64
BC 5300 II	11.8	38.5	4.19	6200	90	28	2.45

H360

1/5/21

old value	12.2	39.0	5.31	5600	74	23	2.83
BC 5300 I	11.8	40.9	5.06	5600	81	25	2.79
BC 5300 II	12.2	40.0	4.75	5500	84	26	2.51

3/5/21

old value	14.5	46.5	5.79	7600	80	25	2.17
BC 5300 I	14.9	42.3	5.33	7200	80	28	2.08
BC 5300 II	14.7	44.3	5.32	7300	83	28	1.94

04/05/21

old value	12.3	38.1	5.01	8800	76	25	2.41
BC-5300-I	12.3	40.8	4.91	8700	83	25	2.65
BC-5300 II	12.3	38.7	4.52	8400	85	27	2.33

34	H_1	H_2	H_3	H_1	H_2	H_3
Range	10.1–15.1	22.–34	25–39	30–48	63–95	56–82
Mean vol	12.6	28	32	39	79	72
			08/04/21			
	13.0	34.5	31.3	32.1	77.1	66.1
	13.2	35.8	32.2	32.9	77.9	68.2
	13.0	36.1	31.6	32.1	80.1	63.9
	13.3	35.0	31.7	32.2	82.1	64.1
	52.5	141.4	126.8	129.8	317.7	262.3
Mean vol	13.1	35.4	31.5	32.5	79.4	65.6
			09/04/21			
Mean vol	12.5	31.5	33.8	32.5	82.9	69.5
			10/04/21			
Mean vol	12.7	30.2	32.7	31.4	81.5	62.8
			12/04/21			
	13.5	29.8	29.6	31.8	70.5	76.3
	12.8	29.7	30.1	31.5	70.6	76.2
	12.3	29.7	29.8	30.8	80.1	71.8
	12.9	30.8	30.2	32.3	70.1	76.3
	52.5	120.10	119.7	126.4	291.4	302.6
Mean vol	13.1	30.0	29.9	31.6	75.4	75.7
			14/04/21			
Mean vol	12.9	32.8	28.9	32.5	81.2	70.9

Haematology – Coagulation profile

Daily Qc 37

Range	10.1 – 15.1	22 – 34	25 – 39	30 – 58	63 – 95	52 – 88
Mean val	12.6	28	32	39	79	72
		23/4/21				
Manual	13.2	29.1	30.5	32.2	85.9	70.9
		24/04/21				
Manual	13.3	32.1	29.8	33.1	87.8	73.4
		26/4/21				
	12.1	31.7	32.8	31.8	78.9	61.4
	12.9	30.5	32.7	32.0	78.0	63.0
	13.4	32.3	32.3	32.3	77.4	64.1
	13.0	32.6	31.3	33.1	76.5	61.9
	52.4	127.1	129.1	129.2	308.8	252.1
Mean val	13.1	31.8	32.2	32.3	77.2	63.0
		27/04/21				
	13.4	32.1	27.7	32.5	81.2	71.7
		28/4/21				
	13.3	30.8	29.6	31.9	83.4	73.4
		29/4/21				
	13.1	28.9		31.3	58.7	
	13.0	29.7		32.0	61.3	
	12.9	29.6		31.7	60.5	
	12.6	30.2		32.1	66.2	
	51.6	118.6		126.1	246.7	
Manual	12.9	29.7		31.7	61.6	

	H_1	H_2	H_3	H_1	H_2	H_3
Range	10.1 – 15.1	22 – 34	25 – 39	30.48	68 – 93	56 – 88
Meanvol	12.6	28	32	39	79	72
		30/4/21				
	13.0	28.7		33.7	72.7	
	12.8	29.0		31.4	78.9	
	13.1	30.0		30.1	73.7	
	13.3	27.3		32.9	75.4	
	52.2	115.0		128.1	300.7	
Meanvol	13.0	28.7		32.0	75.1	
		01/05/21				
Meanvol	13.2	32.5	32.0	32.3	85.2	70.6
		03/5/21				
	12.4	28.3	33.2	31.8	82.3	72.5
	12.7	28.1	33.4	31.9	82.8	76.0
	12.8	28.0	32.9	32.0	82.3	73.2
	13.1	28.5	33.6	32.3	82.5	76.4
	51.0	114.9	133.1	128.0	329.9	307.1
Meanvol	12.7	28.	33.2	32.0	82.4	76.7
		04/05/21				
	12.7	27.4		32.0	77.8	
		05/05/21				
	13.0	28.6		32.2	81.9	

kit opened on 6/5/21

H1 - L No 309105 Sep-22
H2 310103 Aug-22
H3 40 317101 Jul-22

	H1	H2	H3	H1	H2	H3
Range	10.2 - 15.8	21 - 32.5	28 - 29	30.6	58-78	84.8
Mean	13.0	27.0	35	38	64	82
		07/05/21				
Mean	12.7	28.3		33.1	81.6	
		08/05/21				
Mean	12.6	30.5	33.1	31.7	68.8	85.6
	PT	10/5/21				
	12.5	28.4		31.0	66.1	
	13.0	28.1		32.8	65.8	
	13.1	27.9		31.9	66.9	
	13.1	28.3		32.4	65.8	
mean	12.9	28.1		32.0	66.1	

10/5 done


mispa-b
20-200µl
1 5 0
mispa-b
5 .0


REMI R-8C BL


MISPA i2
1. Run Test
2. Function
ESC
FEED
PRINT
ENTER
DEL
1
2
3
4
5
6
7
8
9
0
MISPA-i2


Elanpro™
Elanpro
TARSONS

MISPA-i_2

AGAPPE

CRP

15 Tests, 30 Tests
12009020, 12009002

Intended Use
This reagent is intended for *in vitro* quantitative determination of C-reactive protein in human serum or plasma.
-Nephelometry methodology
-Linear upto 320 mg/L
-Ready to use reagents
-No sample dilution needed.
-No calibration required
-Lower Detection Limit of 0.5 mg/L

Clinical Significance
CRP (C – reactive Protein) is a cytokine induced acute phase protein that increases in concentration as a result of inflammation. CRP levels in the body has been used as a marker or indicator of infections and inflammation. The assay of CRP is more sensitive than the erythrocyte sedimentation rate (ESR) and leukocyte count. The CRP levels return to reference ranges more rapidly after the disease has subsided.

Principle
CRP samples binds to specific anti-CRP antibodies, which have been adsorbed to latex particles and agglutinates. The agglutination is directly proportional to the quantity of CRP in the sample.

Kit Components

Reagent/ Component	Product Code 12009020	Product Code 12009002	Description
CRP R1	1 x 3.0 mL	1 x 5.3 mL	Glycine buffer solution
CRP R2	1 x 3.0 mL	1 x 5.3 mL	Latex suspension coated with anti-CRP antibodies.(rabbit polyclonal antibody)

Risk & Safety
Material Safety data sheets (MSDS) will be provided on request.

Reagent Preparation
CRP R1, R2 Reagents are ready to use

Reagent Storage and Stability
The sealed reagents are stable upto the expiry date stated on the label, when stored at 2 - 8°C.

Open Vial Stability
Once opened the reagents are stable for 75 days. .
The validity of the smart card will be up to 75 days from the date of insertion and activation of the card in Mispa *i2*.

Reagent Deterioration
Turbidity or precipitation in any kit component indicates deterioration and the component must be discarded. Values outside the recommended acceptable range for the Agappe Protein control may also be an indication of reagent instability and associated results are invalid. Sample should be retested using fresh vial of reagent.

Precaution
Bring the reagents to room temperature (RT) before use.
To avoid contamination, use provided cuvettes and pipette tips for dispensing the reagent & sample. Close reagent bottles immediately after use. Avoid direct exposure of reagent to light. Do not blow into the reagent bottles.
This reagent is only for IVD use and follow the normal precautions required for handling all laboratory reagents.

Waste Management
Reagents must be disposed off in accordance with local regulations.

Sample
Fresh serum (Do not use lipemic or hemolysed sample)

Interferences
No interference for

Bilirubin	up to	10 mg/dL
Haemoglobin	up to	500 mg/dL
Intrafat	up to	500 mg/dL
Rheumatoid Factor	up to	500 IU/mL

Materials provided
CRP R1 & R2 Reagents
Smart Card, Cuvettes & Pipette Tips

Test Procedure
The test procedure and the calibration data is provided in the smart card along with the kit. Insert the smart card and follow the instructions.
Step 1:
Insert card to card reader slot & display will prompt to add R1+Sample
Step 2:
Pipette 150 µL R1 & 5 µL sample to cuvette & place the cuvette into cuvette holder
step 3:
After incubation display will prompt to add R2
Step 4:
Pipette 150 µL R2 using attached sensor pipette to the cuvette
Step 5:
The result will show in the display and print out

Calibration
The calibration data is incorporated in the smart card and hence no calibration is required.

Quality Control
It is recommended to use Agappe Protein Control(Bi Level) (Product Code: 11614007) to verify the performance of the assay. Each laboratory has to establish its own internal quality control scheme and procedure for corrective action, if control do not recover within the acceptable range.

Reference Range
It is recommended that each laboratory should establish its own reference values. The following value may be used as guide line.

Serum up to 6 mg/L

Results obtained for patient samples are to be correlated with clinical findings of patient for interpretation and diagnosis.

Performance
1. Linearity
The reagent is linear up to 320 mg/L. If the concentration is greater than linearity, dilute the sample with normal saline and repeat the assay. Multiply the result with dilution factor.
2. Comparison
A comparison study has been performed between Agappe reagent and another internationally available reagent yielded a correlation coefficient of $r^2 = 0.976$ and a regression equation of $y = 1.0843x$.
3. Precision

	Intra Run		Inter Run	
Control	Level 1	Level 3	Level 1	Level 3
n	20	20	20	20
Mean (mg/L)	5.95	51.85	6.17	51.31
SD	0.13	1.77	0.87	1.42
CV(%)	2.25	3.41	1.41	2.76

Accuracy (mg/L)		
Control	Expected Value	Measured Value
Control Level 1	5.85 ± 1.17	5.95
Control Level 2	27.3 ± 5.4	24.6
Control Level 3	51.8 ± 10.3	51.85
Protein Control	7.8 ± 1.8	7.8

4. Sensitivity
Lower detection Limit is 0.5 mg/L

Bibliography

1. Tillett.W.S *et al*:serological reactions in pneumonia with a non protein samatic fraction of *Pneumococcus*.J.Exp.Med..52,561(1930).
2. Zeigenhagen G,Drahovshy D.Klinishe Bedeutung des C-reaktiven protein.Med klin 1983;78:45-50.
3. Rifal.N.Tracy.R.P.Ridker,P.M.clinical efficacy of an Automated High sensitivity C-Reactive protein Assay..45-12.

SYMBOLS USED ON THE LABELS

IVD IN VITRO DIAGNOSTIC USE | SEE PACKAGE INSERT FOR PROCEDURE | LOT LOT NUMBER | MANUFACTURER'S ADDRESS | MANUFACTURING DATE | EXPIRY DATE | TEMPERATURE LIMIT

AGAPPE DIAGNOSTICS LTD.
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REV. NO.: ADL/IFU/CRP/I2/R03

CE ISO 9001:2015
EN ISO 13485:2016

MISPA-i_2

AGAPPE

ASO

15 Tests, 30 Tests
12009016, 12009001

Intended Use
This reagent is intended for *in vitro* quantitative determination of Anti Streptolysin – O (ASO).

-Nephelometry methodology
-Ready to use reagents
-No sample dilution required
-Linear up to 1000 IU/mL
-No calibration required
-Lower Detection Limit of 50 IU/mL

Clinical Significance
ß-hemolytic streptococcus bacteria especially group A, C and G, produce an exotoxin known as Streptolysin-O. People infected with this bacterium produce an antibody Anti Streptolysin-O (ASO). Measuring the levels of ASO is effective for diagnosing, judging the progress of medical treatment and assessing the recovery from diseases like rheumatic fever, acute glomerulonephritis and tonsillitis.

Principle
When an antigen-antibody reaction occurs between ASO in the sample and streptolysin-O which has been sensitized to latex particles, agglutination occurs. The agglutination is directly proportional to the quantity of ASO in the sample.

Kit Components

Reagent/ Component	Product Code 12009016	Product Code 12009001	Description
ASO R1	1 x 3.8 mL	1 x 6.8 mL	Glycine buffer solution
ASO R2	1 x 2.3 mL	1 x 3.8 mL	ASO Latex suspension particles coated with Streptolysin - O

Risk & Safety
Material Safety data sheets (MSDS) will be provided on request.

Reagent Preparation
ASO R1, R2 Reagent are ready to use

Reagent Storage and Stability
The sealed reagents are stable upto the expiry date stated on the label, when stored at 2 - 8°C.

Open Vial Stability
Once opened the reagents are stable for 60 days. .
The validity of the smart card will be up to 60 days from the date of insertion and activation of the card in Mispa *i2*.

Reagent Deterioration
Turbidity or precipitation in any kit component indicates deterioration and the component must be discarded. Values outside the recommended acceptable range for the Agappe Protein control may also be an indication of reagent instability and associated results are invalid. Sample should be retested using fresh vial of reagent.

Precaution
Bring the reagents to room temperature (RT) before use.
To avoid contamination, use provided cuvettes and pipette tips for dispensing the reagent & sample. Close reagent bottles immediately after use. Avoid direct exposure of reagent to light. Do not blow into the reagent bottles.
This reagent is only for IVD use and follow the normal precautions required for handling all laboratory reagents.

Waste Management
Reagents must be disposed off in accordance with local regulations.

Sample
Fresh serum / plasma (Do not use lipemic or hemolysed sample)

Interferences
No interference for

Bilirubin up to	20 mg/dL
Haemoglobin up to	500 mg/dL
Intrafat up to	5000 mg/dL

Materials provided
ASO R1 & R2 Reagents
Smart Card, Cuvettes & Pipette Tips

Test Procedure
The test procedure and the calibration data is provided in the smart card along with the kit. Insert the smart card and follow the instructions.

Step 1:
Insert card to card reader slot & display will prompt to add R1+Sample
Step 2:
Pipette 200 µL R1 & 5 µL sample to cuvette & place the cuvette into cuvette holder
Step 3:
After incubation display will prompt to add R2
Step 4:
Pipette 100 µL R2 using attached sensor pipette to the cuvette
Step 5:
The result will show in the display and print out

Calibration
The calibration data is incorporated in the smart card and hence no calibration is required.

Quality Control
It is recommended to use Agappe Protein Control(Bi Level) (Product Code: 11614007) to verify the performance of the assay. Each laboratory has to establish its own internal quality control scheme and procedure for corrective action, if control do not recover within the acceptable range.

Reference Range
It is recommended that each laboratory should establish its own reference values. The following value may be used as guide line.

Serum up to 200 IU/mL(adults) and 100 IU/mL (children < 5 years)

Results obtained for patient samples are to be correlated with clinical findings of patient for interpretation and diagnosis.

Performance
1. Linearity
The reagent is linear up to 1000 IU/mL. If the concentration is greater than linearity, dilute the sample with normal saline and repeat the assay. Multiply the result with dilution factor.

2. Comparison
A comparison study has been performed between Agappe reagent and another internationally available reagent yielded a correlation coefficient of $r^2 = 0.9565$ and a regression equation of $y = 0.9624x$.

3. Precision

	Intra Run		Inter Run	
Control	Level 1	Level 3	Level 1	Level 3
n	20	20	20	20
Mean (IU/mL)	102.39	248.16	103.11	249.74
SD	2.87	5.40	1.23	3.08
CV(%)	2.8	2.17	1.2	1.23

Accuracy (U/L)		
Control	Expected Value	Measured Value
Control Level 1	121 ± 24.1	105.7
Control Level 3	284 ± 57	257
Protein Control	155 ± 29.4	156.0

4. Sensitivity
Lower detection Limit is 50 IU/mL

Bibliography

1. Galuin, J.P. *et al.*: particle enhanced photometric immune assay system, Clin. Lab Assays (pap .Annu.clin.Lab.Assays Conf.)
2. Singer J.M. *et al.* The latex fixation test Application to the serologic diagnosis or rheumatoid arthritis ,AmerJ.Med 21, 888(1956)

SYMBOLS USED ON THE LABELS

IVD IN VITRO DIAGNOSTIC USE | SEE PACKAGE INSERT FOR PROCEDURE | LOT LOT NUMBER | MANUFACTURER'S ADDRESS | MANUFACTURING DATE | EXPIRY DATE | TEMPERATURE LIMIT

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REV. NO.: ADL/IFU/ASO/12/R02

ISO 9001:2015
CE EN ISO 13485:2016

CE

TYPHOCHEK®

WIDAL ANTIGEN SET / ANTIGENS FOR TUBE TESTS

INTENDED USE

TYPHOCHEK® is a Widal tube agglutination test that detects the presence the serum agglutinins (O, H) found in the serum of patients with typhoid and paratyphoid fever.

SUMMARY

Enteric fever occurs when pathogenic microorganisms like *S. typhi, S. paratyphi A, S. paratyphi B* and *S. paratyphi C* infect the human body. During the course of disease, the body responds to this antigenic stimulus by producing antibodies whose titre rises slowly in early stages, to a maxima and then slowly falls till it is undetectable. Antibodies to *Salmonella* organisms may be detected in the patient serum from the second week after onset of infection. Information regarding the titres and whether or not they are rising or falling can be obtained by performing serological tests using TYPHOCHEK® antigen suspensions. Usually tube titres of 1:80 and above are taken as diagnostically significant, however for endemic areas higher cut-offs may need to be established.

REAGENT

TYPHOCHEK® contains ready to use coloured, smooth antigen suspensions of the bacilli; *S. typhi 'O', S. typhi 'H', S. paratyphi 'AO', S. paratyphi 'BO', S. paratyphi 'AH', S. paratyphi 'BH', S. paratyphi 'CH' and S. paratyphi 'CO'*. TYPHOCHEK® reagents are versatile and standardized for use in a standard tube test procedure for the detection of *S. typhi* and *S. paratyphi* antibodies in the patient's serum.
Each batch of reagents undergoes rigorous quality control at various stages of manufacture for its specificity and performance.

REAGENT STORAGE AND STABILITY

(1). Store the reagents at 2-8°C. DO NOT FREEZE. (2).The shelf life of reagents is as per the expiry date mentioned on the reagent bottle labels. Do not use beyond expiry date. Keep the reagents away from direct sunlight. (3).Once opened the shelf life of the reagent vial is as described on the reagent vial label provided it is not contaminated.

PRESENTATION

Σ	4 x 50 ml	50 ml	50 ml	50 ml	50 ml	50 ml	50 ml	50 ml	50 ml
REF	105310450	105320050	105330050	105340050	105350050	105380050	105360050	105370050	105390050
Antigens	O, H, AH, BH	O	H	AO	BO	CO	AH	BH	CH
PACKAGE INSERT	1	1	1	1	1	1	1	1	1

ADDITIONAL MATERIAL REQUIRED

Timer, Kahn tubes / test tubes, Pipettes (0.1ml, 1 ml), Isotonic saline, Incubator (37°C), Test tube rack.

PRINCIPLE

When the coloured, smooth suspension of attenuated TYPHOCHEK® antigen suspensions are incubated with the patient serum, anti-*Salmonella* antibodies present in the patient's serum react with the antigen suspensions to produce agglutination.
Agglutination is a positive test result, indicating presence of *Salmonella* antibodies in the patient's serum. No agglutination is a negative test result indicating absence of *Salmonella* antibodies in the patient's serum.

NOTE

(1). In vitro diagnostic reagent for laboratory and professional use only. Not for medicinal use. (2). The *S. typhi 'O', S. paratyphi 'CO'* reagents contains 0.5% Phenol, *S typhi 'H', S. paratyphi 'AH', S. paratyphi 'BH', S. paratyphi 'CH'* reagents contain 0.3% Formaldehyde and *S. paratyphi 'AO', S. paratyphi 'BO'* reagents contain 0.7% Ethanol along with 0.1% Sodium azide as preservative. Avoid contact with skin and mucosa. Do not breathe vapour. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Sodium azide may react with lead and copper in plumbing and form highly explosive metal oxides, on disposal flush with large quantities of water. (3).The reagent can be damaged due to microbial contamination or on exposure to extreme temperatures. It is recommended that the performance of the reagent be verified with the positive and negative controls. (4). Shake the reagent vials well before use to disperse the antigen suspension uniformly and improve test readability. (5). It is necessary to use the calibrated dropper provided in the reagent vial to dispense a reagent drop. (6). Only a clean and dry glass tubes must be used. Clean the glass tubes with distilled water and dry. (7). TYPHOCHEK® antigen suspensions are not from human sources hence contamination due to HBsAg and HIV is practically excluded. (8). Do not use damaged or leaking reagents.

SAMPLE COLLECTION AND STORAGE

(1).No special preparation of the patient is required prior to sample collection by approved techniques. Do not use haemolysed and turbid samples. (2). Clean and dry glassware free from detergents must be used for sample collection. (3). Do not heat inactivate the serum. (4).Though freshly collected serum is preferable, store samples at 2-8°C in case of delay in testing, for upto 72 hours.

TEST PROCEDURE

1. Bring reagents to room temperature before testing.
2. Shake and mix antigens well before dispensing.
3. Carefully label test tubes for sample and reagent identity when more than one antigens is used during test procedure.

STANDARD TUBE TEST METHOD

1. Take appropriate number of sets (as required; one set for each antigen suspension) of 8 Kahn tubes / test tubes and label them 1 to 8.
2. Pipette into tube No. 1 of all sets 0.9 ml of isotonic saline.
3. To each of the remaining tubes (2 to 8 of each set) add 0.5 ml of isotonic saline.

MISPA-i_2

AGAPPE

RF

15 Tests, 30 Tests
12009034, 12009003

Intended Use

This reagent is intended for *in vitro* quantitative determination of Rheumatoid factor in Serum.

-Nephelometry methodology
-Linear up to 100 IU/mL
-No sample dilution required
-Ready to use reagents
-No calibration required
-Lower Detection Limit of 10 IU/mL

Clinical Significance

Rheumatoid Factor (RF) is an auto antibody against human IgG commonly seen in serum of patients with rheumatoid arthritis. The measurement of RF value is useful in evaluating the diagnosis, effects of therapy and prognosis of RA, systemic lupus erythematosus, Chronic hepatopathy etc.

Principle

When a sample containing rheumatoid factor is added to denatured human IgG which has been sensitizied to latex particles, antigen-antibody reaction occurs leading to agglutination. The agglutination is proportional to the quantity of RF in the sample.

Kit Components

Reagent/ Component	Product Code 12009034	Product Code 12009003	Description
RF R1	1 x 3.8 mL	1 x 6.8 mL	Glycine Buffer Solution
RF R2	1 x 2.3 mL	1 x 3.8 mL	Latex suspension coated with denatured human IgG

Risk & Safety

Material Safety data sheets (MSDS) will be provided on request.

Reagent Preparation

RF R1 & R2 Reagents are ready to use

Reagent Storage and Stability

The sealed reagents are stable upto the expiry date stated on the label, when stored at 2 - 8°C.

Open Vial Stability

Once opened the reagents are stable for 60 days. .

The validity of the smart card will be up to 60 days from the date of insertion and activation of the card in Mispa *i2*.

Reagent Deterioration

Turbidity or precipitation in any kit component indicates deterioration and the component must be discarded. Values outside the recommended acceptable range for the Agappe Protein Control may also be an indication of reagent instability and associated results are invalid. Sample should be retested using fresh vial of reagent.

Precaution

Bring the reagents to room temperature (RT) before use.

To avoid contamination, use provided cuvettes and pipette tips for dispensing the reagent & sample. Close reagent bottles immediately after use.Avoid direct exposure of reagent to light. Do not blow into the reagent bottles.

This reagent is only for IVD use and follow the normal precautions required for handling all laboratory reagents.

Waste Management

Reagents must be disposed off in accordance with local regulations.

Sample

Fresh serum (Do not use haemolized or lipemic sample

Interferences

No interference for

Bilirubin up to	*20 mg/dL*
Haemoglobin up to	*10 g/dL*
Lipids up to	*10 g/L*

Materials provided

RF R1& R2 Reagents
Smart Card, Cuvettes & Pipette Tips

Test Procedure

The test procedure and the calibration data is provided in the smart card along with the kit. Insert the smart card and follow the instructions.

Step 1:

Insert card to card reader slot & display will prompt to add R1+Sample

Step 2:

Pipette 200 µL R1 & 20 µL sample to cuvette & place the cuvette into cuvette holder.

Step 3:

After incubation display will prompt to add R2

Step 4:

Pipette 100 µL R2 using attached sensor pipette to the cuvette

Step 5:

The result will show in the display and print out

Calibration

The calibration data is incorporated in the smart card and hence no calibration is required.

Quality Control

It is recommended to use Agappe Protein Control (Bi Level) (Product Code: 11614007) to verify the performance of the assay. Each laboratory has to establish its own internal quality control scheme and procedure for corrective action, if control do not recover within the acceptable range.

Reference Range

It is recommended that each laboratory should establish its own reference values. The following value may be used as guide line.

Serum up to 18 IU/mL

Results obtained for patient samples are to be correlated with clinical findings of patient for interpretation and diagnosis.

Performance

1. Linearity

The reagent is linear up to 100 IU/mL.

If the concentration is greater than linearity (100 IU/mL), dilute the sample with normal saline and repeat the assay. Multiply the result with dilution factor.

2. Comparison

A comparison study has been performed between Agappe reagent and another internationally available reagent yielded a correlation coefficient of $r^2 = 0.9569$ and a regression equation of $y = 0.9835x$.

3. Precision

	Intra Run		Inter Run	
Control	Level 1	Level 3	Level 1	Level 3
n	20	20	20	20
Mean (IU/mL)	23.96	39.04	24.89	40.86
SD	0.98	2.16	1.04	1.25
CV(%)	4.10	5.42	4.19	3.07

Accuracy (IU/mL)		
Control	Expected Value	Measured Value
Control Level 1	23.8 ± 4.8	23.4
Control Level 3	37.9 ± 7.6	39.2
Protein Control	28.5 ± 7	28

4. Sensitivity

Lower detection Limit is 10 IU/mL

Bibliography

1. Frederick, Wolfe *et al.* ; Arthritis and Rheumatism 1991: 34; 951-960

SYMBOLS USED ON THE LABELS

IVD IN VITRO DIAGNOSTIC USE | SEE PACKAGE INSERT FOR PROCEDURE | LOT LOT NUMBER | MANUFACTURER'S ADDRESS | MANUFACTURING DATE | EXPIRY DATE | TEMPERATURE LIMIT

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E-Office Computer No: 337817 Dated: 04-05-2021.

CIRCULAR

As per orders of the Director – Cum – VC, SVIMS, this is to inform that the following faculty were kept i/c to take care of NABL related activities:

1. Dr. Aruna K Prayaga MD, Professor, Department of Pathology as Laboratory Director.
2. Dr. M.M. Suchitra MD, Professor, Department of Biochemistry as NABL Quality Manager.

The above orders will come into force with immediate effect.

//BY E-OFFICE ORDER OF THE DIRECTOR CUM VC, SVIMS//

REGISRAR

To: All the above concerned.
Copy to : The HOD, of Pathology, SVIMS,
: The HOD, of Biochemistry, SVIMS,
: The A.D (Estt.Section)i/c, SVIMS.
: File.

Signed by Sreedhar Babu
Date: 04-05-2021 15:57:11
Reason: Approved

Date	Time	July, 2021	Aug, 2021	Sep, 2021	Oct, 2021	Nov, 2021	Dec, 2021
1	8.00 am	6°c	6°C	6°C			
	4.00 pm	5°c	5°C	5°C			
2	8.00 am	8°c	6°C	6°C			
	4.00 pm	7°c	5°C	7°C			
3	8.00 am	6°C	6°C	6°C			
	4.00 pm	8°c	5°C	7°C			
4	8.00 am	5°C	7°C	6°C			
	4.00 pm	8°c	6°C	6°C			
5	8.00 am	6°C	7°C	7°C			
	4.00 pm	8°C	6°C	7°C			
6	8.00 am	7°C	5°C	6°C			
	4.00 pm	7°C	6°C	5°C			
7	8.00 am	7°C	5°C	7°C			
	4.00 pm	8°C	6°C	6°C			
8	8.00 am	7°C	7°C	10°C			
	4.00 pm	8°C	6°C	8°C			
9	8.00 am	9°C	7°C	8°C			
	4.00 pm	9°C	8°C	6°C			
10	8.00 am	8°C	8°C	7°C			
	4.00 pm	8°C	7°C	8°C			
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	4.00 pm	8°C	6°C	6°C			
12	8.00 am	8°C	7°C	7°C			
	4.00 pm	8°C	8°C	6°C			
13	8.00 am	7°C	6°C	6°C			
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	4.00 pm	8°C	7°C				
31	8.00 am		8°C				
	4.00 pm						

Sri Venkateswara Institute of Medical Sciences,

Tirupathi-517501

Document Name :	**HOSPITAL INFECTION CONTROL MANUAL**
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Approved By :	**Designation : Co-Chairman** **Name : Dr. Aloksachan** **Signature :**
Responsibility of Updating :	**Designation: Head of Department of Microbiology** **Name : Dr K.K.Sharma** **Signature :**

HOSPITAL INFECTION CONTROL MANUAL

AMENDMENT SHEET

S.No	Section no & page no	Details of the amendment	Reasons	Signature of the preparatory authority	Signature of the approval authority

INTRODUCTION

The Hospital Infection Control (HIC) Manual for Healthcare is a reference guide containing policies as well as procedures to prevent Health care associated infections (HAI) among patients and staff.

It may not be possible to eradicate all hospital-related infections. However, an effective infection Control program provides optimum protection for both the organization.

The purpose of this manual is to help all healthcare workers to achieve the best possible infection control measures. The overall aim of this document is to provide evidence-based information on the prevention and control of infection. To fulfill this aim a Hospital Infection Control Committee (HICC) needs to be formed that will look after the infection control needs of the SVIMS.

SVIMS recognizes the control of healthcare associated infections as an important issue and is committed to fulfilling its responsibility by ensuring that proper safeguards are instituted to identify and prevent HAI. All aspects of hospital function are included in this activity.

CONTROL OF THE MANUAL

The holder of the copy of this manual is responsible for maintaining it in good and safe condition and in a readily identifiable and retrievable manner.

The holder of the copy of this Manual shall maintain it in current status by inserting latest amendments as and when the amended versions are received.

Infection Control Nurse responsible for issuing the amended copies to the copyholders and the copyholder should acknowledge the same and he/she should return the obsolete copies to the Infection Control Nurse.

The amendment sheet, to be updated (as and when amendments received) and referred for details of amendments issued.

The manual is reviewed once a year and is updated as relevant to the hospital policies and procedures. Review and amendment can happen also as corrective actions to the non-conformities raised during the self-assessment or assessment audits by NABH.

The authority over control of this manual is as follows:

Preparation	Approval	Issue
Infection Control Officer	Chairman of HICC	Accreditation Group Leader

The procedure manual with original signatures of the above on the title page is considered as 'Master Copy', and the photocopies of the master copy for the distribution are considered as 'Controlled Copy'.

Distribution List of the Manual:

S.No.	Designation
1	Chairman
2	Infection Control Officer
3	Accreditation Group Leader

Surveillance

Purpose:

To develop and implement a system for surveillance of infections to include:

• To identify baseline information about the frequency and type of healthcare-associated infections

• To recognize clusters or significant deviations from endemic level.

• To develope a system for identifying, reporting, and analyzing the incidence and causes of healthcare-associated infections

• To perform a risk assessment of the needs for the institution on at least a yearly basis

• To prepare staff and physicians to identify and report early any clusters of patients with similar symptoms to HICC and/or local health department and to conduct appropriate tests

Evidence of periodic surveillance activities: Surveillance is done actively in the following cases:

a. Hospital acquired infections

- Catheter Associated Urinary Tract Infection (CAUTI)
- Central Line Associated Bloodstream Infection (CLABSI)
- Surgical site infection (SSI)
- Ventilator associated pneumonia (VAP)

b. Bed sore analysis

c. Needle-stick injuries

d. Multidrug-resistant organisms:

- Methicillin Resistant *Staphylococcus aureus* (MRSA)
- Methicillin Resistant *Coagulase negative Staphylococcus* (MRCONS)
- Vancomycin Resistant *Enterococci* (VRE)/Vancomycin resistant *Staphylococcus aureus (*VRSA*)*

e. Environmental surveillance

1. Procedure
2. Define the frequency and mode of surveillance
3. National and international guide lines
4. Any demolition / repair area in high risk area
5. Active and passive surveillance
6. Parameters to be achieved

a.Methods of Surveillance*

Fumigation and Random Culture from High Risk Areas

HICC decided that culture swab to be taken from critical areas once in a month or when an infection is suspected. Take the swabs according to the table shown below. The request of sample to be approved by the Infection Control Officer.

The original copy of the culture report to be filed in the infection control department and a copy of the report to be filed in the concerned department as well.

Surveillance Culture Schedule

S.NO	Department	Duration	Period for surveillance culture	Period for Fogging	Weekly cleaning	Air culture
1	**ALL OT's**	WEEKLY	Monthly once (Sunday)	Every Sundays, day before any major surgeries &any infected cases notified	Every Sunday& SOS	Monthly once
2	**All Intensive care units (ICU)**	WEEKLY	Every month & SOS	Every month & SOS	Monthly	Once in 6months
3	**Casualty Procedure room**		Every month	Every 3rd month	Every Sunday	Once in 6months
4	**Labour room**		Every month & SOS	Every month & SOS		

5	**Endoscopy**		Every month & SOS	Every month & SOS		
	Emergency Medicine	WEEKLY	Every month & SOS	Every month & SOS	Monthly	Once in 6months
6	**CSSD**		Every month & SOS	Every month & SOS		
7	Hemodialysis unit and Renal transplantation	WEEKLY	Every month & SOS	Every month & SOS	Monthly	Once in 6months
8	Laboratories/ sample collection centres		Every month & SOS	Every month & SOS	Monthly	Once in 6months
9	Blood bank	WEEKLY	Every month & SOS	Every month & SOS	Monthly	Once in 6months
10	Dental clinic		Every month & SOS	Every month & SOS	Monthly	Once in 6months
11	Drinking water	DAILY	Every month & SOS	Disinfection with chlorine solution- Weekly & SOS	Monthly	Water Culture monthly

URINARY TRACT SURVEILLANCE

Surveillance for CAUTI is done from the day of catheterization till one day after catheter removal.

Date of event (DOE): Earliest date when symptom or culture used to meet UTI criteria becomes positive.

Infection Window Period: 7 days period ranging from the date of first positive diagnostic test, 3 days before and three days after.

Indwelling catheter (or Foley catheters): A drainage tube that is inserted into the urinary bladder through the urethra, is left in place, and is connected to a drainage bag (including leg bags).

- If catheters are used for intermittent or continuous irrigation- included for UTI surveillance.
- Condom or straight in-and-out catheters, Nephrostomy tubes, ileoconduits, or Suprapubic catheters are not included for UTI surveillance.

If catheter is removed and reinserted:

- ¬ If catheter is reinserted on day of catheter removal or the next day- Urinary catheter day count will continue
- ¬ If catheter is reinserted there after- Urinary catheter day count will be started as new catheter day.

Location of attribution: The inpatient location where the patient was assigned on DOE of UTI.

Transfer Rule: If a patient is transferred from location A to B, then:

- If DOE is on the day of transfer or the next day- Event attributes to location A
- If DOE is thereafter – Event attributes to location B.

Multiple Transfers rule: Attribute the UTI to the first location in which the patient was housed the day before the UTI's DOE.

UTI INFECTION CRITERIA FOR SURVEILLANCE

SYMPTOMATIC UTI (SUTI):

SUTI 1a- Catheter –associated SUTI (CA-SUTI)

Must meet with all the three criteria which occurred during IWP only.

1. **Catheter criteria-** catheter in place for > 2 calendar days (day of device placement= Day 1). If removed-then DOE must be on the day of removal or on next day AND
2. **Symptom criteria-** At least one of the following :
   Fever (>38˚ C), Suprapubic pain or tenderness*, costovertebral angle pain or tenderness*, urgency, frequency, dysuria. AND

   (* without any other cause, considered only when catheter is not in place).

   - Suprapubic tenderness (sign) or pain (symptom)- such as Suprapubic or lower abdominal pain or bladder/pelvis discomfort (not generalized abdominal pain)
   - Costovertebral angle pain/ tenderness – Left or right lower back pain not generalized low back pain)

3. **Urine culture Criteria-** 1 or 2 organisms isolated with atleast one organism of $\geq 10^5$ CFU/ml.
   (>2 organisms – taken as contaminants)

   ($<10^5$ CFU/ml: not considered for surveillance if clinically significant).

SUTI 1b (Non- CA-SUTI)- Same as Ia except the catheter criteria is not met.

SUTI 2- CAUTI or Non-CAUTI in <1 year of age

1. **Catheter criteria**- If met- called as CA-SUTI, if not met-called as CA-SUTI
2. **Symptom criteria-** Atleast one of the following: Fever (>38˚ C), hypothermia (<36˚ C), apnea*, bradycardia*, lethargy*, vomiting*, Suprapubic tenderness* (* without any other cause)
3. **Urine culture criteria-** Same as 1a
   The following are excluded organisms for UTI surveillance- *Candida* species or yeast, mold, dimorphic fungi or parasites.

ASYMPTOMATIC BACTEREMIC URINARY TRACT INFECTION (ABUTI)

All elements must occur during infection window period (IWP)

1. **Catheter criteria**- If met- called as CA-SUTI, if not met-called as CA-SUTI

2. **Symptom criteria-** No signs or symptoms of SUTI (**except** For patient >65 years of age without catheter may have a fever and still meet the ABUTI criterion)
3. **Urine culture criteria-** Same as 1a
4. **Blood culture criteria-** One matching organism of urine should be isolated from blood.

Note:

Urine culture positive means- 1 or 2 organisms isolated atleast one organism of $\geq 10^5$ CFU/ml.

Symptoms means-

- **All age-** At least *one of the following:* Fever (>38˚ C), Suprapubic pain or tenderness*, costovertebral angle pain or tenderness*, urgency, frequency, dysuria.
- **< 1year age-** Atleast *one of the following:* Fever (>38˚ C), hypothermia (<36˚ C), apnea, bradycardia, lethargy, vomiting, suprapubic tenderness.

Catheter associated means- Catheter in place for > 2 calendar days; if removed then DOE must be on the day of removal or on next day

Blood culture positive means- Blood culture must have at least one matching organism to that of urine culture.

Reporting of CAUTI for allocation in a specific period should be done as the following:
CAUTI rate= No. Of CAUTI/ No. Catheter days x1000 (Both CA-SUTI and CA-ABUTI are taken as CAUTI)
DUR (Device utilization ratio)= No. Catheter days/ No. Of patient days

BLOOD STREAM INFECTION EVENT SURVEILLANCE

Surveillance for CLABSI is done from the day of central line till one day after the catheter removal.

Date of event (DOE): Earliest date when the first element (i.e. symptom/ culture) used to meet laboratory-confirmed bloodstream infection (LCBI) criteria becomes positive.

Infection Window Period: 7 days period ranging from the date of first positive diagnostic test (blood culture, sample collection date), 3 days before and three days after.

CENTRAL LINE:

An intravascular catheter that terminates at or close to the heart or in one of the great vessels which is used for infusion, withdrawal of blood, or hemodynamic monitoring.

The following are considered great vessels for the purpose of NHSN surveillance:

- Aorta
- Pulmonary artery
- Superior venacava
- Inferior venacava
- Brachiocephalic vein
- Internal jugular vein
- Subclavian veins
- External iliac veins
- Common iliac veins
- Femoral veins
- In neonates, the umbilical artery/ vein (Umbilical catheter)

Notes

- Neither the insertion site nor the type of device may be used to determine if a line qualifies as a central line. Peripherally inserted central lines (PICC lines) are also considered as CL surveillance.
- Central line if migrated- Still considered as CL for surveillance.

The **following devices** are **NOT** considered central lines*

- Arterial catheters, Arteriovenous fistula, Arteriovenous graft
- Extracorporeal membrane oxygenation (ECMO), Hemodialysis reliable outflow (HERO)
- Peripheral IV or Midlines
- Pacemaker wires and other non-lumened devices (as fluids not infused)
- Non-accessed central lines (not accessed nor inserted during the hospitalization)

Types of central lines:

- Temporary CL : (non – tunneled, non – implanted)
- Permanent CL : Tunneled catheters, implanted catheters – used for outdoor patients (e.g. patients on chemotherapy)

LCBI INFECTION CRITERIA FOR SURVEILLANCE

Laboratory – Confirmed Blood stream Infection Criteria

LCBI – Must meet one of the following criteria:		
LCBI 1	For pathogens, Any age	Patient of any age has a NHSN pathogenisolated in one blood culture and organism(s) identified in blood is not related to an infectionat other site
LCBI 2	For commensal > 1 year	Patient of > 1 year age, has a NHSN commensal isolated in two blood culture AND Any one symptom : fever (> 100.4˚F) ,chills, or hypotension
LCBI -3	For commensal ≤ 1 year	Same as LCBI 2 – except for the symptom criteria. Any one symptom – fever (>100.4˚ F), hypothermia

		(<96.8˚F), bradycardia, apnea
CLASBSI: Any type of LCBI is considered as CLABSI if CL criteria is fulfilled		
Central line criteria	Central line in place for > 2 calendar days (day of device placement = Day 1). If removed – then DOE must be on the day of removal or on next day.	

Mucosal Barrier Injury Laboratory –Confirmed Bloodstream Infection (MBI-LCBI)

MBI-LCBI (subsets of LCBIs): Must meet one of the following criteria	
MBI-LCBI 1	Patient of any age meets CLBI criterion-1 with one blood culture positive **for ONLY intestinal organisms** form the MBI-LCBI organisms list (refer page 4-25),And patient meets at least one of the following : 1.Allogeneic hematopoietic stem cell transplant recipient 2.Netropenic patient
MBI-LCBI 2	**MBI-LCBI 1 except** with one blood specimen yielding viridians streptococci
MBI-LCBI 3	**MBI-LCBI 2 except** patient of ≤ 1year of age
Note: ANC /WBC levels should not be used to set the IWP or to identify the date of event. Date of the LCBI would be the date of the MBI-LCBI even.	

Notes:

- **Admitted to hospital with implanted central line in place:** if the patient is admitted or transferred in to a facility with an implanted central line (port) in place, and if the patient's only central line, then **the day of first access** (line placement, insertion of needle into the port, infusion or withdrawal though the line) in an inpatient locations considered as **central line Day 1.**
- Blood stream infections will not be reported if they occur within the Repeat Infection Timeframe (RIT) of a previously identified BSI.
- Only primary BSIs create a BSI RIT. Secondary BSIS do not create a BSI RIT.
- CLABSIs will not be reported if Group B Streptococcus detected in blood during the first 6 days of line.
- **Common NHSN commensal organisms include , but not are not limited to –**

- *Pseudomonas species and Acinetobacter species*
- *Coagulase negative staphylococci (including S.. epidermidis)*
- *Diphtheroids (Corynebacterium ssp. Not C.diphtheriae)*
- *Viridans group streptococci*
- *Bacillus species (not B.anthracis) and propionibacterium species*
- *Aerococcus species, Micrococcus and Rhodococcus species*

- Full commensals list ,refer CDC site http://www.cdc.gov/nhsn/xls/master-organism-com-commensals-lists.xlsx
- **Following pathogens are Not included as LCBI pathogens:** *Campylobacter spp. C.difficile, Enteropathogenic E.coli, Salmonella species, Listeria species ,Yersinia species* and dimorphic fungi.
- **Reporting instruction** for commensals/pathogens : *Staphylococcus species* and *Staphylococcus epidermidis* report as Staphylococcus epidermidis
- **Two separate blood specimen means:**
  - Should be collected at same day or two consecutive days from two sites or two lumens of same CL, one peripheral /one CL.
  - Only criterion is – should undergo two separate decontamination.
- If pus collected from the insertion site of non-CL . Vascular access devises (refer above *) and has matching organisms from blood culture- Report as vasculitis, not as CLABSI
- Catheter tip culture –not used to determine CLABSI
- Purulent phlebitis-considered as CVS-VASCULITIS ,not CLABSI
- Secondary BSI : to be reported if _
  - Site specific infection has a matching organism with blood culture during 2 BSI-AP
  - Blood culture is used as a site specific infection criteria (refer 4-27 for detail list)

Reporting of CLABSI for a location in a specific period should be done as the following:
CLABSI rate= No. of CLABSI/No. of central line days X 1000
DUR (Device utilization ratio)=No. of central line days/No. of patient days

VENTILATOR-ASSOCIATED EVENT (VAE) AND VENTILATOR- ASSOCIATED PNEUMONIA (VAP) SURVEILENCE

VAP and other healthcare-associated pneumonias are important, common HAIs. Earliesr PNEU/VAP criteria used for surveillance had suffered challenges because of lack of objective, reliable definitions. Hence NHSN had introduced in 2013 more objective surveillance criteria, VAE. Currently, NHSN has adopted both the surveillance criteria for ventilated patients –VAE and PNEU/VAP.

- VAE (ventilator-associated events) criteria should be used for surveillance in adult locations
- PNEU/VAP criteria should be used for surveillance in pediatric locations and may also be used for off-plan surveillance(who are not reporting to NHSN) in adult as an alternate to VAE criteria.
  - o Patient with > 18 years in PICU - surveillance is done as per PNEU/VAP
  - o Patients with <18 years in adult ICU – are excluded from surveillance

VENTILATOR – ASSOCIATED EVENT (VAE) (For use in adult locations only)

The VAE definition algorithm is meant to use only for surveillance; it is not a clinical definition algorithm and is not intended for use in the clinical management of patients.

The earliest date of event for VAE (the date of onset of worsening oxygenation) is day 3 of mechanical ventilation

Definition of VAE:

There are three events described under VAEs such as VAC, IVAC, and PVAP. All the three events are identified by using a combination of objective criteria such as i) deterioration in respiratory status after a period of stability or improvement on the ventilator, ii) evidence of infection or inflammation, and iii) laboratory evidence of respiratory infection.

Ventilator- Associated Events(VAE) Surveillance Algorithm	
MV criteria	Patient has mechanical ventilator (MV) in place for 2 days or

	more or if removed: MV was in place on the day of sample collection or the day before	
Baseline period	Patient should have a baseline period of stability which is defined as ≥ 2 days of stable or decreasing daily minimum FiO2 or PEEP	
Ventilator- Associated Condition (VAC)	After a baseline period, the patient should have at least one of the following criteria of worsening of oxygenation- •↑Daily minimum FiO2* of ≥ 0.20 sustained for ≥ 2 days or •↑ Daily minimum PEEP** values of ≥ 3 cm H2O sustained for≥ days	
Infection – related Ventilator- Associated complication (IVAC)	During the infection window period *** of VAC, patient should have both : 1) Temperature >100.4□ or < 96.8□ ,OR WBC count ≥ 12,000 or ≤ 4,000 cells/mm^3 and 2) A new antimicrobial agents (S)[#]is started, and continued for ≥ 4 days (QAD)[##]	
Possible Ventilator-Associated Pneumonia (PVAP)	During the infection window period *** of IVAC and ONE of the following :	
	Criterion 1	Positive quantitative/semi quantitative culture (ET aspirate ≥ 10^5 CFU/ml; BAL ≥ 10^4CFU/ml; Lung tissue ≥ 10^4CFU/g; protected specimen brushing ≥ 10^3 CFU/ml
	Criterion 2	Gram stain shows purulent respiratory secretions@ plus positive culture of any growth (in sputum or specimens of Criterion 1
	Criterion 3	One of the following positive tests : • Organism identified from pleural fluid • Lung histopathology • Diagnostic test for Legionella species • Diagnostic test for respiratory viruses[@@]

Note:

***Fraction of inspired oxygen:** Fraction of oxygen in inspired gas (FiO_2 of ambient air is 0.21; the oxygen concentration of ambient air is 21%).

- In patients on MV, the FiO_2 is one of the key parameters that can be adjusted depending on the patient's oxygenation needs from 0.3 to 1.0 (30%-100%).
- It's normally maintained at <0.3(30%). An increase of $FiO_2 \geq 0.2$ (20%) is considered abnormal.

**** Positive End –Expiratory Pressure:** A technique used to maintain airway pressure greater than atmospheric pressure at the end of exhalation by the introduction of a mechanical impendence to exhalation. PEEP values ranges from 0 to 15 cm H_2O and a value of 0-5 cm H_2O is considered baseline. An increase of ≥ 3cm H_2O (i.e. 8 or more) is considered abnormal.

Daily minimum PEEP/FiO_2: The lowest value during a calendar day that is set on the ventilator and maintained for at least 1 hour.

- **PEEP/FiO_2,** if recorded less frequently than once per hour, then the lowest value set on the ventilator during the calendar day should be taken as daily minimum.
- **PEEP/FiO_2**, if recorded more frequently than once per hour (i.e. keeps changing), then the lowest value recorded for that day is taken as daily minimum
- **Date of event:** Date of onset of worsening oxygenation first calendar day in which the daily **PEEPorFiO$_2$** increases above the thresholds.

****VAE Window Period :** It is 5 – day period which includes the 2 days before, the day of, and the 2 days after the VAE event date.(Exception: MV day 1 or day 1 are not included in window period. So, if DOE is on MV day 3 or 4, in such case VAE window period will be reduced to 4 days or 3 days respectively).

Why first MV day 1 and 2 excluded from window period- this is intended to exclude inflammatory and infectious sings present on the first two days of mechanical ventilation because they are more likely to be due to pre- existing conditions than ventilator- acquired complications.

 # New antimicrobial agent: Defined as any agent that is-

- Should be started during VAE window period
- Should be continued at least 4 days
- Should not be given at least in preceding two days

##Qualifying Antimicrobial Day (QAD): a day on which the patient was administered an antimicrobial agent that was determined to be "new" within the VAE window period.

- Gap of < 1 day – Counted as qualifying antimicrobial day (QAD)
- Gap of > 2 days and two different antimicrobial agent – Do not count as QAD

@Purulent Respiratory Secretions: Secretions from the lungs, bronchi, or tracheal that contain >25 neutrophils and <10 squamous epithelial cells per low power field.

@@Respiratory viruses – Influenza virus, respiratory syncytial virus, adenovirus, Para influenza virus, rhinovirus, human metapneumovirus and corona virus.

Reporting instruction:

- Hierarchy of definitions within VAE : Report highest order of infection (e.g. if patient meets criteria for VAC,IVAC and PVAP , report PVAP)
- Pathogens are not reported for VAC or IVAC events; it's reported only for PVAP events.
- Secondary BSI s are not reported for VAC or IVAC; it's reported only for PVAP events only when PVAP is diagnosed based microbiological criteria(histopath excluded).
- Patients on high frequency ventilation or extracorporeal life support or brain dead are EXCLUDED from VAE surveillance.
- Lung expansion devices such as intermittent positive-pressure breathing (IPPB); nasal positive end-expiratory pressure (nasal PEEP); and continuous nasal positive airway pressure (CPAP, hypoCPAP) are not considered ventilators unless delivered via tracheostomy or endotracheal intubation (e.g., ET-CPAP,ET-BIPAP).
- Patients on conventional mode of MV while in the prone position; nitric oxide therapy; helium-oxygen mixtures, epoprostenol therapy are INCLUDED in VAE surveillance
- Airway pressure Release Ventilation (APRV) is INCLUDED for VAE surveillance, but only $\mathbf{FiO_2}$ is used to determine worsening of oxygenation, not PEEP.
- A new VAE cannot be reported until 14- day period of an existing VAE (RIT is not used for VAE).
- Location of attribution, transfer rule and re-intubation rule are same as followed for other DAIs.
- Normal respiratory flora is excluded from pathogens list of PVAP.
- Candida or yeast not otherwise specified; Coagulase- negative Staphylococcus and Enterococcus are considered as commensal for all respiratory specimens except for lungs tissue and pleural fluid where they are taken as pathogens.
- Dimorphic fungi are excluded from surveillance as they are community associated.

- No culture microbiology technique to identify the pathogen such as PCR, antigen detection can also be considered for diagnosis of PVAP.
- Reactivation of HSV or CMV pneumonitis is not considered for surveillance.

PNEUMONIA (VENTILATOR-ASSOCIATED (VAP) AND NON- VENTILATOR-ASSOCIATED PNEUMONIA (PNEU) EVENT (for paediatric and immunocompromised in patients)

VAP and other healthcare- associated pneumonias are important, common healthcare- associated infections. VAP diagnosis has long been a challenge because of the lack of objective, reliable definitions. In January 2013 the NHSN replaced surveillance for ventilator- associated pneumonia (VAP) in adult inpatient locations with surveillance for ventilator-associated events (VAE).

PNEU definitions are still available for off-plan PNEU surveillance for mechanically- ventilated adult, paediatric and neonatal patients and non- ventilated adults, paediatric or neonatal patients

VAP (Ventilator Associated pneumonia) Criteria

MV Criteria (Common to all)	Patient has mechanical ventilator (MV) in place for 2 days or more or if removed:MV was in place on the day of sample collection or the day before
Chest X ray Criteria (Common to all)	In two serial chest X- rays: at least one of the following : i)new or progressive persistent infiltrate,ii) consolidation, iii) cavitation iv) pneumatoceles (in infants ≤1 year old) (in patients without underlying pulmonary or cardiac disease – one definitive image is acceptable)
PNEU-1 For < 1yr)	**W**orsening gas exchange (e.g., O2 desaturations (e.g.: pulse oximetry <94 %) Increased oxygen requirements , or increased ventilator demand)
	And at least three of the following:
	i. Temperature instability
	ii. Leukopenia (≤4000 WBC/mm$^{3)}$ or leukocytosis (≥ 15,000 WBC/mm^3) and ≥10% band forms
	iii. New onset of purulent sputum, or change in character of sputum, or increased respiratory secretions or increased suctioning requirements.
	iv. Apnea, tachypnea, nasal flaring with retraction of chest wall or nasal flaring with grunting
	v. Wheezing, rales or rhonchi
	vi. Cough
	vii Bradycardia (<100 beats/min) or tachycardia (>170 beats/min)
PNEU-1 (For 1-12 yr)	At least three of the following:
	i . Fever (>100.4˚F) or hypothermia (<96.8˚F)

	ii. Leukopenia (≤4000 WBC/mm^3)or leukocytosis (≥ 15,000WBC/mm^3)
	iii. New onset of purulent sputum, or change in character of sputum, or increased respiratory secretions or increased suctioning requirements
	iv. New onset or worsening cough or dyspnoea or tachypnea
	v. Rales or bronchial breath sounds
	vi. Worsening gas exchange (e.g., O2 desaturations{e.g.,$PaO_2/FiO_2 \leq$ 240},increased oxygen requirements, or increased ventilator demand)
PNEU-2	At least three of the following :
	i . Fever (>100.4˚F) or hypothermia (<96.8˚F)
	ii. Leukopenia (≤4000 WBC/mm^3)or leukocytosis (≥ 15,000WBC/mm^3)
	And at least one of following (clinical):
	i. New onset of purulent sputum, or change in character of sputum, or increased respiratory secretions or increased suctioning requirements
	ii. New onset or worsening cough or dyspnoea or tachypnoea
	iii. Rales or bronchial breath sounds
	iv. Worsening gas exchange (e.g., O2 desaturations{e.g.,$PaO_2/FiO_2 \leq 240$},increased oxygen requirements, or increased ventilator demand)
	And at least one of the following finding (laboratory):
	i. Blood or pleural fluid culture positive
	ii. Positive quantitative culture from minimally-contaminated LRT specimen (e.g., BAL or protected specimen brushing, lung tissue
	iii. Histopathologic exam shows at least one of the following evidences of pneumonia • Abscess formation or foci of consolidation • Or Evidence of lung parenchyma invasion by fungal hyphae or pseudohyphae.
PNEU-3 (for Immuno-compromised patients	Patient who is Immuno-compromised has at least one of the following (Clinical):
	i .Fever (>100.4˚F)
	ii. For adults ≥ 70 years old, altered mental status with no other recognized cause.
	iii. New onset of purulent sputum, or change in character of sputum, or increased respiratory secretions or increased suctioning requirements
	iv. New onset or worsening cough or dyspnea or tachypnea
	v. Rales or bronchial breath sounds
	vi.Worsening gas exchange (e.g., O2 desaturations{e.g.,$PaO_2/FiO_2 \leq$ 240},increased oxygen requirements, or increased ventilator demand)

	And at least one of the following finding (laboratory):
	i.Blood or pleural fluid culture positive
	ii.Positive quantitative culture from minimally-contaminated LRT specimen (e.g., BAL or protected specimen brushing, lung tissue
	iii.Histopathologic exam shows at least one of the following evidences of pneumonia • Abscess formation or foci of consolidation • Or Evidence of lung parenchyma invasion by fungal hyphae or pseudohyphae.
	iv. Identification of matching candida spp. From blood and sputum, endotracheal aspirate, BAL or protected specimen brushing
	v.Evidence of fungi from minimally contaminated LRT specimen (e.g., BAL or protected specimen brushing) from one of the following : direct microscopic exam or culture or non-culture diagnostic laboratory test.

Note:

- Hierarchy should be maintained (e.g. patient meets criteria for both PNEU-1 and PNEU-2, report PNEU-2)
- Pneumonia due to gross aspiration (e.g. emergency intubation) that meets the PNEU/VAP definition with a date of event during the HAI timeframe is considered HAI.
- Any alternative descriptive wordings used to describe imaging finding of pneumonia such as air-space disease, focal opacification, patchy areas of increased density etc. by the radiologist, in the appropriate clinical setting these should be seriously considered as potentially positive findings.
- Change in character of sputum refers to the color, consistency, odor and quantity.
- Tachypnea
  - In adults, tachypnea is defined as respiration > 25 breaths per minute
  - In pediatric, , tachypnea is defined as respiration > 75 breaths per minute in premature infants born < 37 weeks gestation and until the 40th week: >60 breaths per minute in patients < 2 months old: >50 , tachypnea is defined as respiration > 25 breaths per minute in patients 2-12 months old; and >30 breaths per minute in children >1 year old.
- Rales may be described as crackles.

Immunocompromised patients include:

- Those with neutropenia (absolute neutrophils count or total WBC <500/mm)
- Those with leukemia, lymphoma or who are HIV positive with CD4 count<200/µl

- Those who have undergone splenectomy
- Those who have the history of solid organ or hematopoietic stem cell transplant
- Those on cytotoxic chemotherapy
- Those on steroids daily for >2 weeks.

SURGICAL SITE INFECTION (SSI) EVENT

SSI monitoring requires active, patient-based, prospective surveillance. It includes review of medical records or surgery clinic patient records; daily rounds; surgeon surveys by mail or telephone; patient surveys by mail or telephone.

- Infection window period, present on Admission (POA), Hospital Associated Infection and Repeat infection time frame definitions – Not applicable to SSI.
- **NHSN operative Procedure –** at least **one incision** (including laparoscopic approach and cranial burr holes)mode through the skin or mucous membrane, or reoperation via an incision that was left open during a prior operative procedure.
- Do NOT report procedures done on a brain- dead patient.

Date of event (DOE): Date when the first element used to meet the SSI infection criterion occur for the first time during the SSI surveillance period.

Procedure/Surgery Stat Time (PST): Time when the procedure is begun (e.g., incision for a surgical procedure).

Procedure/Surgery finish (PF): Time when all instrument and sponge counts are completed and postoperative radiologic studies to be done in the OR are completed, all dressings and drains are secured, and the physicians/surgeons have completed all procedure-related activities on the patient.

Secondary **SI Attribution Period for SSI:** 17- day period that includes the date of event, 3 days prior, and 13 days after.

Wound Class Categories

Clean	An uninfected operative wound in which no inflammation is encountered and the viscus is not entered.
Clean- contaminated	Operative wounds in which viscus entered under controlled conditions and without unusual contamination.
Contaminated	Open ,fresh, accidental wounds with major breaks in sterile technique (e.g., open cardiac surgery) or gross spillage from the viscus or Necrotic tissue without evidence of purulent drainage (e.g., dry gangrene)
Dirty or infected :	Includes old traumatic wounds with retained devitalized tissue and those that involve existing clinical infection or perforated viscera. (organism causing postoperative infection may be present at site

	before the operation)

SSI CRITERIA FOR SURVEILLANCE

Superficial incisional SSI : Must meet all of the following criteria:		
1.Time frame		DOE occurs within 30 days of surgery (where day 1= the procedure date)
2.Site		Involved only skin and subcutaneous tissue of the incision
3.Any one of the following:		
A	Purulent pus	Purulent drainage form the superficial incision
B	Culture +ve	Culture positive from an aseptivally – obtained specimen
C	Symptoms	Culture not perfomed, but patient has at least one of the following: Pain or tenderness; localized swwlling: erythema;or heat
D	Surgeon's Diagnosis	Diagnosis of a superficial incisional SSAI by the surgeon or attending physician
Note : The Following do not qualify superficial SSI: • Diagnosis of cellulitis at surgical site • Stitch abscess alone (minimal inflammation) • Localized stab wound or pin site infection • Circumcision is not an NHSN operative procedure. • Infected burn wound.		

Deep incisional SSI : Must meet all of the following criteria:		
1.Time frame		DOE occurs within 30 days or 90 days*of surgery (where day 1= the procedure date)
2.Site		Involves deep soft tissues of the incision (e.g., fascial and muscle layers)
3.Any one of the following:		
A	Purulent pus	Purulent drainage form the deep incision
B	Culture +ve	Culture positive from an aseptically – obtained specimen
C	Symptoms	Culture not performed, but patient has at least one of the following: Fever (>100.4˚F), localized pain or tenderness
D	Other evidence of deep SSI	Abscess or other evidence of infection involving the deep incision that is detected on gross anatomical or histopathogic exam, or imaging test

*Refer the table -1

Organ /space SSI : Must meet all of the following criteria:	
1.Time frame	DOE occurs within 30 days or 90 days*of surgery (where day 1= the procedure date)
2.Site	Infection involves any part of the body deeper that the fascial/muscle layers, that is opened or manipulated during the operative procedure

3.Any one of the following:		
A	Purulent pus	Purulent drainage from a drain that is placed into the organ/space
B	Culture +ve	Culture positive from an aseptically – obtained fluid or tissue in the organ/space
C	Symptoms	Culture not performed, but patient has at least one of the following: Fever (>100.4˚F), localized pain or tenderness
D	Other evidence of organ/space SSI	Abscess or other evidence of infection involving the organ/space that is detected on gross anatomical or histopathogic exam, or imaging test
4.And Meets at least one criterion for a specific organ/space infection site listed in NHSN		

*Refer the table -1

SSI Event Reporting Instructions:

1. Dimorphic fungi are excluded from reporting of SSI

2. Present on Admission (POA) does not apply to the SSI; instead term 'PATOS' is used.

3**. Infection present at time of surgery (PATOS):** PATOS denotes that there is evidence of notable infection (abscess or pus) present preoperatively. The evidence of infection or abscess must be noted/documented intraoperatively in an operative note or report of surgery.

a) Positive culture/path report without surgical documentation of infection is not PATOS

b) Fresh trauma resulting in a contaminated case is not PATOS

c) Colon perforation, necrosis, gangrene, fecal spillage, nicked bowel during procedure, or a note of inflammation- are not consider as PATOS

4. **Multiple tissue levels are involved in the infection**: If different types of SSI (superficial incisional, deep incisional, or organ/space) co- exist, report only the deepest tissue infection.

5. **Primary and non-primary closure incision** – Infection in both primary and non-primary closure incision are reported as respective SSIs

- *Non-primary closure*: Closure of the surgical wound in a way which leaves the skin level completely open following the surgery.
- *Primary closure*: Closure of the skin level during the original surgery, regardless of the presence of wires, wicks, drains, or other devices or objects extruding through the incision.(Including multiple incision and laparoscopic trocar sites).

6. **If multiple operative procedures of same surgery** are done on different dates and if patient develops SSI, report the SSI event to the closest operative day to the infection.

7. **If multiple primary incision sites of the same NHSN** operative procedure become infected, only report as a single SSI.

8. For deep, organ space SSI surveillance for incisional primary is 90 days, incisional secondary is 30 days.

9. **In two different operative procedures at same site done on the same trip to the OR** report the SSI for the highest risk procedure and refer the following table- 2 with decreasing order of risk.

10. If an SSI develops following manipulation after operative procedure except closed manipulation; SSI is attributed to manipulation but not operative procedure.

11. Postoperative accidents, falls, in appropriate showering or patients intentional or unintentional actions should be neglected and report the infection as SSI if infection develops.

Denominator instruction

1. **In two different operative procedure categories at same site done on the same trip to the OR: E**ach procedure is included separately for numerator and denominator and report the highest risk procedure (Table-2).

- CARD and CBGC
- Trauma repair and splenectomy

2 . **Duration of the procedure when more than one NHSN procedure is performed through**

.The same incision – difference between starts time and finish time of whole procedure

. Two Different incisions – average of total duration attributed to both the surgeries

3. **More than one operative procedure through same incision within 24 hours** : Take denominator as one surgery

4. Colon surgeries with a colostomy is taken as one procedure.

5. Laparoscopic hernia repairs are considered one procedure, regardless of the number of hernias that are repaired in that trip to the OR

6.>1 operative procedure of same category through same incision within 24 hours: Take as one event (e.g.; CBGB and CBGC – take as one event)

7. Patient expires in the OR: If a patient expires in the operating room, don't complete a form

Reporting of SSI for a location in a specific period should be done as the following:

SSI rate = No. Of SSI /No. Surgeries performed in same period*100

Table 1. Surveillance periods for SSI following selected NHSN Operative Procedure

30 – day Surveillance			
Code	Operative procedure	Code	Operative procedure
AAA	Abdominal aortic aneurysm repair	LAM	Laminectomy
AMP	Limb amputation	LTP	Liver transplant
APPY	Appendix surgery	NECK	Neck surgery
AVSD	Shunt for dialysis	NEPH	Kidney surgery
BILI	Bile duct, liver or pancreatic surgery	OVRY	Ovarian surgery
CEA	Carotid endarterectomy	PRST	Prostate surgery
CHOL	Gallbladder surgery	REC	Rectal surgery
COLO	Colon surgery	SB	Small bowel surgery
CSEC	Caesarean section	SPLE	Spleen surgery
GAST	Gastric surgery	THOR	Thyroid surgery
HTP	Heart transplant	THYR	Thyroid and / or parathyroid surgery
HYST	Abdominal hysterectomy	VHYS	Vaginal hysterectomy
KTP	Kidney transplant	XLAP	Exploratory Laparotomy
90 day surveillance			
Code	**Operative Procedure**		
BRST	Breast surgery		
CARD	Cardiac Surgery		
CBGB	Coronary artery bypass graft with both chest and donor site incision		
CBGC	Coronary artery bypass graft with chest incision only		
CRAN	Craniotomy		
FUSN	Spinal fusion		
FX	Open reduction of fracture		
HER	Herniorrhaphy		
HPRO	Hip prosthesis		
KPRO	Knee prosthesis		
PACE	Pacemaker surgery		
PVBY	Peripheral vascular bypass surgery		
VSHN	Ventricular shunt		

Note : Superficial incisional SSIs are only followed for a 30 –day period for all procedure types.

Table 2. NHSN Principal Operative category Selection Lists

(The categories with the highest risk of SSI are listed before those with lower risks.

Priority	Code	Abdominal Operations
1	LTP	Liver transplant
2	COLO	Colon surgery
3	BILI	Bile duct, liver or pancreatic surgery

4	SB	Small bowel surgery
5	REC	Rectal surgery
6	KTP	Kidney transplant
7	GAST	Gastric surgery
8	AAA	Abdominal aortic aneurysm repair
9	HYST	Abdominal hysterectomy
10	CSEC	Caesarean section
11	XLAP	Laparotomy
12	APPY	Appendix Surgery
13	HER	Herniorrhaphy
14	NEPH	Kidney surgery
15	VHYS	Vaginal hysterectomy
16	SPLE	Spleen surgery
17	CHOL	Gallbladder surgery
18	OVRY	Ovarian surgery
Priority	**Code**	**Thoracic Operations**
1	HTP	Heart transplant
2	CBGB	Coronary artery bypass graft with donor incision(s)
3	CBGC	Coronary artery bypass graft, chest incision only
4	CARD	Cardiac surgery
5	THOR	Thoracic surgery
Priority	**Code**	**Neurosurgical (Brain/Spine) Operations**
1	VSHN	Ventricular shunt
2	CRAN	Craniotomy
3	FUSN	Spinal fusion
4	LAM	Laminectomy
Priority	**Code**	**Neck Operations**
1	NECK	Neck surgery
2	THYR	Thyroid and or parathyroid surgery

Reference:

1. National Healthcare Safety Network (NHSN) [internet]. Centers for Disease Control and Prevention 2017. Available from: https://wwww/cdc.gov/nhsn/

The collection of surveillance data is an ongoing process in SVIMS.

The infection control team verifies the data on a regular basis.

The surveillance activities in SVIMS also incorporate tracking and analyzing of infection risks, rates and trends.

Monitoring activities includes

The surveillance activity include monitoring of compliance with hand hygiene guidelines

- ϖ Surveillance activities in SVIMS hospital also include monitoring of effectiveness of housekeeping service on a regular basis using a checklist.
- ϖ Report regarding HAI rates is informed to all the departments' monthly wise.
- ϖ SVIMS hospital identifies all **Notifiable** diseases and ensures that this is sent at the specified frequency and in format as required by statutory authorities.

1. Acute diarrheal disease
2. Acute Dysentery – Amoebic / Bacillary
3. Acute flaccid paralysis
4. Cholera or Cholera- like disease
5. Diphtheria
6. Encephalitis
7. Plague
8. Hepatitis-viral
9. Leptospirosis
10. Malaria
11. Measles
12. Meningitis – Pyogenic/ Prescribed disinfectant
13. Rabies
14. Tetanus
15. Enteric fever
16. Pertussis
17. Dengue
18. Chickenpox
19. Chikungunya
20. H1N1(Swine flu)

Infection control program

Purpose: SVIMS hospital supports an Infection control(IC) Program designed to ensure the safety of patients, staff, and visitors within its healthcare environment, and all off-campus sites, by reducing the risk of acquiring a healthcare-associated infection (HAI). The IC Program maintains a culture of safety that promotes zero tolerance for both the occurrence of preventable HAIs and for non compliance with established infection prevention and control practices.

Scope:

- This program is implemented to protect all the hospital patients, employees, and visitors, including medical staff and allied health affiliates.
- This program is an organization wide program that interfaces with all departments and services of the organization and all national and state regulatory agencies concerning infection prevention and control.
- To reduce hospital acquired infection for e.g. Device related infections like catheter associated blood stream infection & procedure related infections like surgical site infections
- To protect employee health by vaccinations, post exposure prophylaxis and limiting exposure to hazardous chemicals.
- To follow policies and procedures throughout the hospital with continuous surveillance, control measures and preventive measures, taken on a daily basis.

a) Sri Venkateswara Institute of Medical Sciences has documented infection prevention and control program (HIC manual) which aims at preventing and reducing risk of health care associated infections.

b) The infection prevention and control program is a continuous process and reviewed annually Infection control committee to maintain consistency with new recommendations and changes within the institution..

SVIMS have an Infection Control Committee which coordinates all infection prevention control & prevention activities.

C)Hospital Infection Control Committee Members:

- **HICC Chairman –** Dr T.S.Ravikumar, Director cum Vice Chancellor
- **HICC Co-Chairman** Dr. Aloksachan**,**Medical Superintendent
- **Member Secretary-** Dr K.K.Sharma,HOD of Microbiology
- **Hospital Infection Control Officers -** Dr.R.Jayaprada, Dr.N.Ramakrishna.
- **Senior Consultant-** Dr A. Mohan, Senior professor& HOD of Medicine-Member
- **All the heads of the departments-** Members
- **Nursing Superintendent-** Mrs.C.Sunitha**-**Member
- **InfectionControlNurses-**V.Karpugam,D.Redemma,A.Shobharani,N.Bayamma-Members
- **Operating theatre In charge-** Mrs Shakira- Member
- **In-charge of Central Sterile Supplies Department-** Mrs. C.Sunitha**-**Member
- **Health inspector –** Mrs. A.Umamaheswari**-**Member
- **In-charge of pharmacy-** Dr. P.Subramanyam**-**Member
- **In-charge of hospital linen-** Mrs. C.Sunitha**-**Member
- **In-charge of hospital laundry-** D.Indiramma**-**Member
- **In-charge of hospital kitchen-** MrsM.Sunitha**-**Member
- **Epidemiologist-** Dr. Ravishankar, Assistant professor, Social & Preventive medicine-Member
- **In-charge of engineering department of hospital –** Kumar**-**Member

d) **Hospital Infection Control Team:**

- **Member Secretary-** Dr K.K.Sharma,HOD of Microbiology
- **Hospital Infection Control Officers -** Dr.R.Jayaprada, Dr.N.Ramakrishna.
- **InfectionControlNurses-**V.Karpugam,D.Redemma,A.Shobharani,N.Bayamma-Members

- **Infection Control technicians:** Mr P.Yashodhar, Mr. P.Rammurthy

e.Objectives of the HICC:

1. To minimize the risk of infection to patients, staff and visitors.
2. To identify the roles and responsibilities of key personnel involved in the prevention and control of infection.
3. **Surveillance:**
    - Hospital acquired infection (HAI) Surveillance- develops a system for identifying, reporting, analyzing, investigating and controlling hospital acquired infections with defined periodicity.
    - Antimicrobial Surveillance (AMR) Surveillance
    - Environmental Surveillance (Air, water, Surface –OT's/ICU and other high risk areas
    - Staff skin flora Surveillance
4. **Disinfectants-**
    - To check for sterilization & disinfection practices in SVIMS
    - In- use testing of disinfectants.

5. Outbreak Investigation-

- Continuous Surveillance of infections for early detection of outbreak for which, appropriate control measures are undertaken.
- Surveillance of any community outbreak viz. Dengue, meningitis, diphtheria, Swine flu, chicken pox etc. to prevent spread within the hospital among health care workers.

6. Monitoring Hospital Biomedical Waste Management (BMW)- In collaboration with Biomedical Waste Management department, HICC aims at monitoring the waste segregation and disposal system.

7. Auditing- HICC conducts regular audits for various aspects such as

- Hand hygiene audit
- BMW (Biomedical Waste Management) audit

8. Needle Stick Injury reporting system

9. Staff Health care Activities- are carried out with objectives

- Vaccinating all the staff /students (especially newly recruited) of SVIMS with Hepatitis B vaccine.

- Regular check of Anti HBs antibody titer of all the staff/students of SVIMS.

10. Monitors the proper use of antibiotics, develops antibiotic policies and recommends remedial measures when antibiotic resistant strains are detected

11. Reporting of Notifiable Diseases with collaboration with department of Social Preventive Medicine (PSM).

12. Prepare the manuals for hospital infection control as well as antimicrobial guideline and review and update hospital infection control policies and procedures from time to time.

13. Education of SVIMS nurses, MBBS students, residents and other staff about principles of infection control and stressing individual responsibility for Infection Control.

14. Meets regularly not less than once a month.

Activities of Infection Control Team:

1. The hospital has an infection control team, which coordinates implementation of all infection prevention and control activities. The team is responsible for day-to-day functioning of infection control program.
2. Maintenance of sound habits in personal hygiene and individual responsibility in infection control by training the s staff throughout the organization.
3. Periodical training of all category staff about Infection Control Protocols & Policies and providing care to personnel for work-related illnesses or exposures..
4. Establish standard operational procedures for Infection Control practices.
5. Introduce new policies and protocols on the method of disinfection and sterilization.
6. To monitor and manage critical incidents
7. To coordinate and conduct regular training activities for the staff to ensure implementation of infection control practices
8. Training of all new employees as to the importance of infection control and the relevant policies and procedures
9. Maintain and implement biomedical waste management protocols.
10. Regular monitoring of Engineering department and water supply system.
11. Supervision of biomedical waste management activities.

Meetings

- The infection control team meets once in a month or otherwise as necessary.
- Documentation of meetings and recommendations are kept by the Document Controller.

- The ICO (Infection Control Officer) Microbiologist & Infection Control Nurse (ICN) conduct inspection in the hospital daily.
- Registers are maintained by ICN

Responsibilities of the Infection Control Team

- Advise staff on all aspects of infection control and maintain a safe environment for patients, visitors and staffs.
- Advise management of "at risk" patients.
- Carry out targeted surveillance of hospital acquired infections and act upon data obtained e.g. investigate clusters of infection above expected levels.
- Provide a manual of policies and procedures for aseptic, isolation and antiseptic techniques (see annexure).
- Define and implement antibiotic policy (see annexure).
- Investigate outbreaks of infection and take corrective measures.
- Provide relevant information on infection problems to management.
- Assist in training of all new employees as to the importance of infection control and the relevant policies and procedures.
- Have written procedures for maintenance of cleanliness.
- Surveillance of infection, data analyses, and implementation of corrective steps. This is to be based on reviews of lab reports, reports from nursing in charge etc.
- Waste management.
- Supervision of isolation procedures.
- Monitors employee health programme pertaining to HAI.

Infection Control Nurse (ICN): ICN is the link between the HICC and the hospital wards/ ICU's. She is the functional unit of HICC who implements the infection control measures in the hospital; identifies the problems associated with implementation of infection control measures and implements the solutions after discussing with infection control officer.

Responsibility of Infection Control Nurse (ICN)

- The duties of the ICN are primarily associated with ensuring the practice of infection control measures by nursing and housekeeping staff.

- Maintaining records and statistics regarding IC activities and maintains HAI incidents record.
- Conducts daily round for HAI surveillance, hand hygiene audits, bundle care audit and disinfection adherence audit.
- Checking by inspection that Infection Control and prescribed disinfectant procedures are being carried out in accordance with hospital policy.
- Checking of housekeeping activities like the use of Personal Protective Equipments usage of proper disinfectant, mopping plan, and biomedical waste management.
- Training of all category staff.
- Liaison between laboratory and ward staff: Informing head of department and giving advice on infection control problems.
- Notification of communicable diseases and other Notifiable disease through telephone and as well as through email & documented in register.
- Arrangements taken to provide hand washing solutions and alcohol based hand rubs.
- Work as a clinical supervisor by ensuring all the established policies and protocols are practiced like hand washing procedures, use of hand rubs, isolation policies, care of IV and vascular access, urinary catheters, universal precautions, housekeeping, cleaning and disinfection, PPE, equipment cleaning, etc
- Ensure health checkup of all employees.
- Monitoring engineering activities like maintenance of aqua guard registers and cleaning register of water tanks etc.
- Immediate attentions in Needle Stick Injury & Post exposure prophylaxis.
- In addition the ICN **conducts infection control rounds and maintains the registers**.
- The ICN is also involved in **education of paramedical staff including nurses and housekeeping staff**.

Infection Control lab technician (ICLT):

Infection Control lab technician is a technician working in the department of Microbiology and posted in HICC. He /She have the following responsibility.

Duties of Infection Control lab technician (ICLT):

- Air and surface surveillance culture for OT, ICU's and other high risk areas- Involves in fixing the schedule (biannual and random), then collecting the specimen and then processing & identification.
- Performing water surveillance to test the quality for drinking water of hospital campus and other areas of the city.
- Performing rapid diagnostic tests for blood borne viruses in cases of needle stick injury.
- Staff Surveillance of MRSA and other MDRO's.
- Performing disinfectant testing of a range disinfectant before selection of the products during the annual tender.
- Sterility checking of blood and blood product samples obtained from blood bank.

Hospital Infection Control Officer (HICO):

The Hospital Infection Control Officers (HICO) of SVIMS is a faculty from department of Microbiology. He is overall responsible for activities of Hospital Infection Control team (HICT) and reports directly to the medical superintendent.

Duties of Hospital Infection Control Officer (HICO)

The Microbiologist/ nodal officer serve as Infection Control Officer.

- Coordinate with the medical superintendent (Co-Chairman) in planning infection control programme and measures.
- The ICO is responsible for surveillance and supervision of hospital acquired infection as well as preventive and corrective programmes in the hospital.

<u>Surveillance and Reporting of Infection</u>

- Surveillance for infection can be active or passive.

a. Passive Clinical Surveillance & Reporting:

- Clinicians suspecting occurrence of HAI may report this to ICO.
- All details regarding the patient, procedures, medication, etc. are made available.
- The Lab in-charge of the microbiology department is responsible for reporting any information about infections suspected to be hospital acquired.

b. Active Surveillance & Reporting:

High risk areas of the hospital are identified as:

Operation theatres, Intensive care units, Labour room, Causality procedure room, Endoscopy Room, Emergency Medicine, Hemodialysis unit and Renal transplantation, CSSD (Central Sterile Services Department), Laboratories/ sample collection centres, Blood bank, Dental clinic, Food handlers ,Drinking water.

- Keeps a track of any developing outbreaks: both consulting with microbiological & clinical team regularly.

Surveillance is done actively in the following cases:

- a. Hospital acquired infections:
  - Catheter Associated Urinary Tract Infection (CAUTI)
  - Central Line Associated Bloodstream Infection (CLABSI)
  - Surgical site infection (SSI)
  - Ventilator associated pneumonia (VAP)

- b. Bed sore analysis

¬ Participate, guides in research activities related to infection control practices and publish them.

¬ Supervise the activities of department of biomedical waste.

¬ Ensuring safe laboratory practices to prevent infection in staff.

¬ Develops guidelines for sterilization, disinfection practice of the hospital.

¬ Review and revision of Infection control Manual of SVIMS.

Common HAIs and their prevention

Definition of Healthcare associated infection

"HAI refers to infections that patients acquire during the course of receiving treatment for other conditions or that HCWs acquire while performing their duties within a healthcare setting".

Hospital acquired infections

- Catheter Associated Urinary Tract Infection (CAUTI)
- Central Line Associated Bloodstream Infection (CLABSI)
- Surgical site infection (SSI)
- Ventilator associated pneumonia (VAP)

Bed sore analysis

Needle-stick injuries

Multidrug-resistant organisms:

- Methicillin Resistant *Staphylococcus aureus* (MRSA)
- Methicillin Resistant *Coagulase negative Staphylococcus* (MRCONS)
- Vancomycin Resistant *Enterococci* (VRE)/Vancomycin resistant *Staphylococcus aureus(VRSA)*

Prevention: To prevent healthcare-associated infections in patients, staff, and visitors through:

- Education of patients, staff, and visitors about infection prevention and control guidelines and methods.
- To review and evaluate the procedures.
- To maintain a system to monitor and improve adherence to hand hygiene and precaution policies
- To determine whether precautions are appropriate in individual patients by conducting Infection Prevention rounds
- To ensure adequate preparation for surge of infectious patients (i.e., beds, PPE, equipment, linens)
- To communicate with the Pharmacy Review Committee in regard to antibiotic utilization practice patterns and antimicrobial stewardship actions
- To participate in construction and renovation planning and activities
- To plan for emergency management of infectious patients (bioterrorism, chemical terrorism, pandemic, or outbreak)

Policy on high risk areas

Purpose: To maintain standards in infection control measures and minimize hospital acquired infections in high risk areas of the hospital.

- To define policy and procedure regarding hospital acquired infections in high risk areas of the hospital.

Scope: The following are applicable to Hospital**.**

- Document infection control procedure for high risk areas.
- Conduct training.
- Surveillance and monitoring.
- Develop action plan and function accordingly.

SVIMS Hospital implements infection control programme in all areas which includes emergency room, trauma bay, post-operative ward, Blood bank, dress changing rooms, visitor's room, special rooms (Low-Moderate risk areas) apart from high risk areas.

SVIMS Hospital identified various **high risk areas*** and procedures, and has policies to prevent infection in these areas.

<u>High risk areas of the hospital are identified as</u>

1. Operation Theatres
2. Intensive care units
3. Causality procedure room
4. Obstetrics and Labour room
5. Cardiac catherization Lab
6. Endoscopy Room
7. Emergency Medicine
8. Hemodialysis and renal transplantation units
9. CSSD (Central Sterile Services Department)
10. Laboratories/ sample collection centers
11. Blood bank
12. Dental clinic

13. Food handlers
14. Drinking water

Policy on Standard precautions

Purpose:

1. To promote a safety climate.
2. To develop policies which facilitate the implementation of infection control measures
3. To prevent cross infection
4. To break the chain of infection

Most common mode of transmission of pathogens is via HANDS

Scope: The following are applicable to Hospital**.**

- Documentation of standard precautions
- Conduct training.
- Surveillance and monitoring.
- Develop action plan and function accordingly.

Concept of Standard Precautions:

There are a number of precautions designed to protect health care workers from exposure to blood borne pathogens. While majority of patients infected with HIV/HBSAg/ HCV are asymptomatic at the time of presentation, all patients are considered as having potentially infectious blood and body fluids. Precautions may vary based on anticipated exposure.

Features of universal precautions:

1. Use of Personal Protective Equipments

a) Mask-Protection from air bone infections or situation which lead any splash or sprays of blood and body fluid

b) Glove –Use glove when we are touching the hand with blood and body fluids, secretions any wound, or any other contaminated items.

c) Apron-Any Chances of splash or contamination on soiling.

d) Goggles –During positive cases (OT &LR).

e) Boots-If necessary.

f) Caps are worn whenever indicated.

2. Prevention of injury with sharps:

Sharps injuries commonly occur during use of needles and surgical instruments and after use during disposal.

Precautions to be observed:

1. Needles should not be recapped, bent or broken by hand.

2. Disposable needles & other sharps should be discarded into puncture resistant containers at the site of procedure.

3. Sharps should not be passed from one HCW (Health Care Worker) to another. The person using the equipment should discard it. If necessary a tray can be used to transport sharps.

4. All sharps containers to be discarded when 3/4ths full.

Policy on Hand hygiene

Purpose:

1. To remove dirt and debris
2. To decontaminate the hands
3. To prevent cross infection
4. To break the chain of infection

Scope: The following are applicable to hospital**.**

- Hand hygiene surveillance and monitoring
- Conduct training.
- Develop action plan and function accordingly.

Hand Washing

Hand washing means vigorous rubbing of hand with soap and water or with any antiseptic agents.

Types

1. Social hand wash
2. Procedure hand wash
3. Surgical hand wash

Purpose

1. To remove dirt and debris
2. To decontaminate the hands
3. To prevent cross infection
4. To break the chain of infection

Most common mode of transmission of pathogens is via HANDS

"Hand washing is the single most important means of preventing the spread of infection"

When?

- ¬ Before and after duty.
- ¬ Before each invasive procedures.

- ¬ Before and after using gloves.
- ¬ After touching of blood or body fluid.
- ¬ Before and after touching patients.
- ¬ Before touching invasive devices.
- ¬ After toileting, urination

Indications for Hand Hygiene

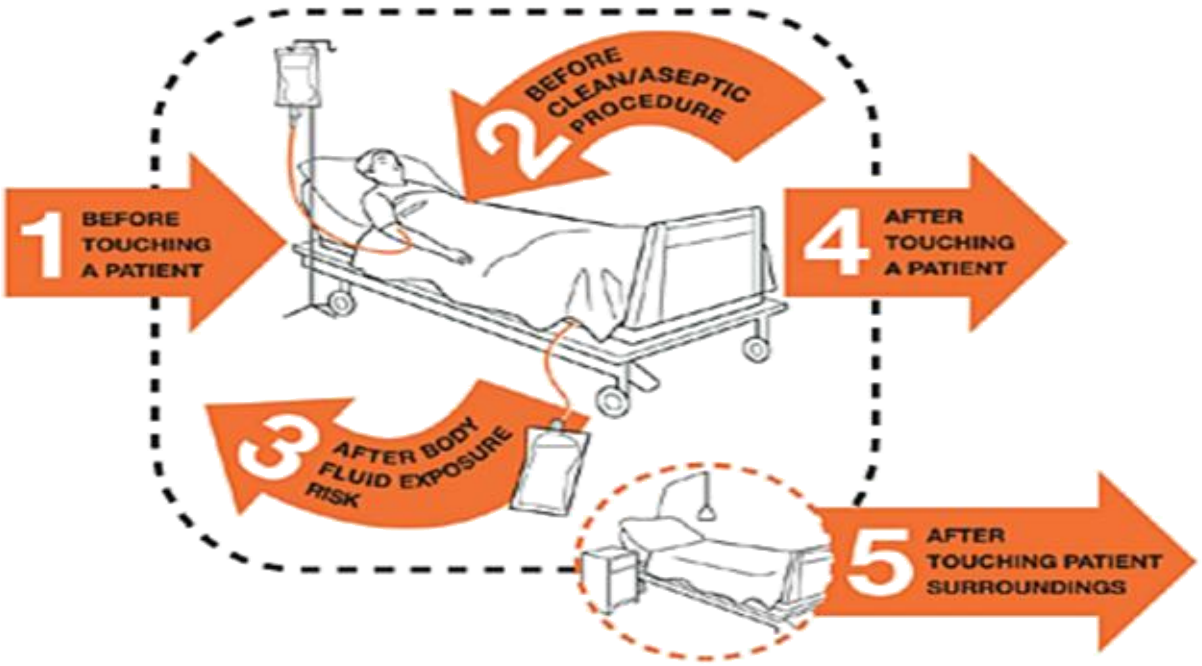
- ¬ When hands are visibly dirty, contaminated, or soiled, wash with non-antimicrobial or antimicrobial soap and water.
- ¬ If hands are not visibly soiled, use an alcohol-based hand rub for routinely decontaminating hands.

WHO's Five (5) Moments in Hand Hygiene-

Hand hygiene must be practiced –

1. Before touching a patient.
2. Immediately before performing a clean or aseptic procedure, including handling an invasive device for patient care, regardless of whether or not gloves are used.
3. Promptly after contact with body fluids, excretions, mucous membranes, non-intact skin, or wound dressings regardless of whether or not gloves were used.
4. After touching a patient and his/her immediate surroundings, even when leaving the patient's side.
5. After contact with inanimate objects (including medical equipment and furniture) in the immediate vicinity of the patient.

Perform hand wash when hands are visibly dirty.



Courtesy: WHO/CDC

Specific Indications for Hand Hygiene

Before:

a) Patient contact

b) Donning gloves when inserting a CVC

c) Inserting urinary catheters, peripheral vascular catheters, or other invasive devices that don't require surgery

After:

a) Contact with a patient's skin

b) Contact with body fluids or excretions, non-intact skin, wound dressings

c) Removing gloves

1. Social hand washing (10 -15 sec)

Indications

1. Before handling food
2. After visiting toilet
3. Before and after nursing the patient (Bathing and bed making)
4. It can be used in community and public places.

2. Procedure hand washing or hygienic hand washing (30sec -1mt)

Indications

1. Before each invasive procedures
2. Before attending immunocompromised patients
3. Before and between caring for high risk patients
4. Before and after use of gloves
5. After touching of blood or body fluid

Methods of Hand Washing

1. Wet hands with running water.

2. Obtain soap or detergent that contains antimicrobial agents spread all area of the hands.

3. Vigorous rubbing of hands (all area) about 30 sec to 1 min.

4. Wash hands thoroughly with running water.

5. Rinse and dry.

6. Turn off water with using paper towel or use elbow to close the tap handle

Steps of Procedure Hand Washing

Courtesy: WHO/CDC

1. Palm to Palm

2. Right palm over left dorsum and left over right dorsum.

3. Palm to palm finger interlocked.

4. Back of finger to opposing palms with finger interlocked.

5. Rotational rubbing of right thumb clasped in left palm and vice versa

6. Rotational rubbing, backwards and forwards with clasped fingers of right hand in left palm and vice versa.

7. Rotational rubbing of right wrist and vice versa. Dry thoroughly.

3. Surgical Hand Wash (3-5mts)

1. Prior to all operative procedures

2. Prior to treatment of all burns cases

3. Before insertion of all invasive devices (cardiac catheterization, Insertion of all lines especially arterial and central venous catheterization).

Method

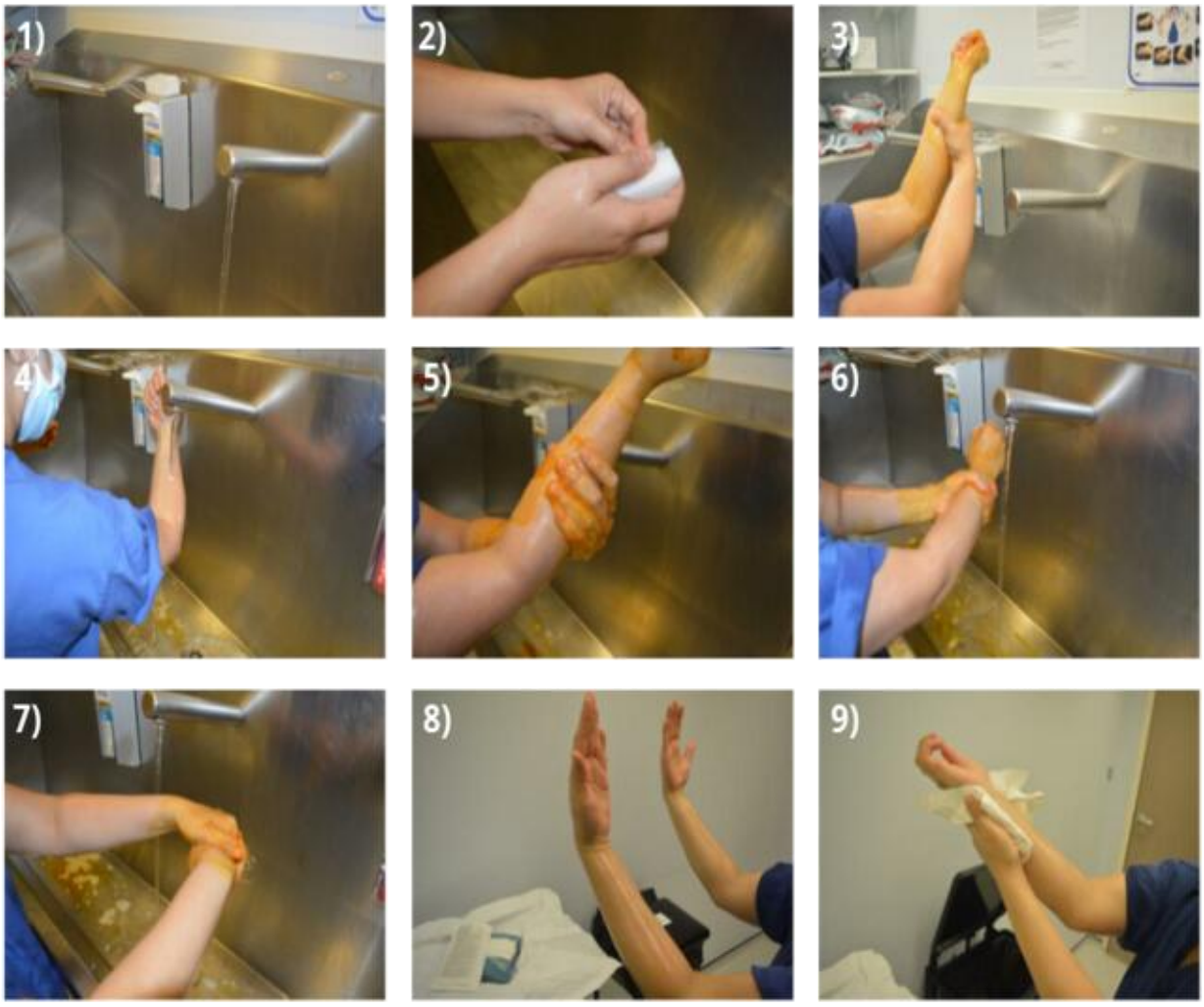
1. Hands are washed up to the elbow freely using disinfectant.

2. Scrubbing of fingers, space between fingers and nails, brush used to scrub the nails

3. Wash hands thoroughly with running water & after wash the tap should be closed with elbow

4. Keep the hand finger upright position.

5. Dry the hand with sterile towel.



Courtesy: WHO/CDC

Hand Rub

In Chlorhexidine /alcohol 70% hand rub in all areas

When?

I.Before touching invasive devices

ii. After touching the patient

iii. Before handling the patient

iv. Before preparing any injections

A Third dimension in hand-hygiene

Policy on Transmission based precautions

Purpose:

1. To prevent transmission based infections
2. To decontaminate the hands
3. To prevent cross infection
4. To break the chain of infection

Scope: The following are applicable to Hospital**.**

- Hand hygiene surveillance and monitoring
- Conduct training on transmission based precautions .
- Develop action plan and function accordingly.
- To procure adequate isolation rooms.

Define Infection

SVIMS adheres to transmission based precautions at all times. Infection is the invasion and multiplication of microorganisms. Hospital infection control is important for patients, health care workers and public .The Infection control Team plays a major role in the prevention and control of nosocomial infections.

Successful infection prevention and control involves implementing work practices that prevent the transmission of infectious agents through a two-tiered approach including:

1. Standard precautions: Routinely applying basic infection prevention and control strategies to minimise risk to both patients and healthcare workers, such as hand hygiene, personal protective equipment, cleaning and appropriate handling and disposal of sharps

2. Transmission-based precautions (specific precautions): Additional precautions taken based on the specific transmission of the diseases where standard precautions may not be sufficient on their own--these specific interventions control infection by interrupting the mode of transmission.

For better understanding the additional precautions taken with respect to transmission of the diseases, a knowledge of transmission of infectious agent is necessary (table-1 and table-2).

Table-1: Transmission of infectious agents can occur in a number of ways.

Route	**Description**
1. Contact transmission	
Direct transmission	i)Transmission through direct skin to skin

		(hands) ii)Ingestion , iii) Injection
	Indirect transmission	Through a contaminated object or person.
2. Droplet transmission		Can occur when an infected person coughs,sneezes or talks and during certain procedures Droplets are infectious particles >5μm in size Droplet distribution is limited by the force of expulsion and gravity and usually travels short distance (I meter) Droplets can also be transmitted indirectly to mucosal surfaces (e.g. hands)
3. Airborne transmission		Small-particle (< 5 μm) aerosols are created during breathing talking coughing or sneezing and secondarily by evaporation of larger droplets in conditions of low humidity. aerosols can be dispersed over long distances (>1 meter) by air currents and inhaled by susceptible individuals. small particles can transmit infection into small airways of the respiratory tract
4. Other modes of Transmission		Common sources such as contaminated food, water medications, devices or equipment.

CONTACT PRECAUTIONS

1) What are the risks?

•Direct transmission occurs when infectious agents are transferred from one person to another person without a contaminated intermediate object or person

- E.g: Through ingestion, injection, or hands

•Indirect transmission involves the transfer of an infectious agent through a contaminated intermediate object (fomites) or person.

- E.g: Contaminated clothing, patient-care devices, environmental surfaces

•Examples: MDROs, skin infection. bronchiolitis, Burkholderia cepacia. Chicken pox, Chlamydia, Clostridium difficile. conjunctivitis, CMV. Diphtheria. VRE, Gonorrhoea. Hepatitis A, E, HSV, leprosy. scabies.

2) How should contact precautions be applied?

Key aspects of applying contact precautions include

A, Hand hygiene and PPE.

•Effective hand hygiene is important and the 5 moments for hand hygiene should be followed at all times

•In C,difficile or non-enveloped viruses (e.g. rotavirus) diarrhoea- Use 4% chlorhexidine hand wash (Alcohol based rubs not useful).

•Putting on both gloves and gown upon entering the patient-care area helps to contain infectious agents.

•A surgical mask and protective eyewear must be worn if there is the potential for generation of splashes or sprays of blood and body substances into the face and eyes

•Remove gown and gloves and perform hand hygiene before leaving the patient-care

B. Patient care equipment for patients on contact precaution

•use patient-dedicated equipment or single-use non-critical patient-care equipment (e.g. blood pressure cuffs, nebulisers, mobility aids).

•If dedicated equipment is unavoidable, clean the equipment and allow it to dry before use on another patient,

C. Patient placement

- A single-patient room is recommended
- Keep patient notes outside the room
- Keep patient bedside charts outside the room
- Disinfect hands upon leaving room and after writing in the chart
- Keep doors closed
- If single room is not available

- avoid placing these patients with patients who are at increased risk of an adverse outcome from infection
- change protective attire and perform hand hygiene between contact with patients in the same mom

D. Transfer of patients

- Limit transfer of patient as much as possible.
- If transfer within or between facilities is necessary, it is important to ensure that infected or colonised areas of the patient's body are contained and covered_
- PPE should be put on before the patient is handled at the destination

DROPLET PRECAUTIONS

1) What are the risks?

- Infectious agents that are transmitted through respiratory droplets (i_e. large-particle droplets :>51un in size) that are generated by a patient who is coughing, sneezing or talking)
- Transmission via large droplets requires close contact as droplets generally only travel short distances (<1mcire).
- Examples: respiratory syncytial virus (RSV), MAL7oplavna pneumonia, parainfluenza, pertussis. plague and meningococcus.

2) How should droplet precautions be applied?

The key aspects of applying droplet precautions include:

A. Hand hygiene and PPE

- Droplet transmission is a form of contact transmission and some infectious agents transmitted by the droplet route may also be transmitted by contact till is therefore an important aspect.
- The surgical mask should be put on upon room entry, with practiced before putting on the mask and after taking off the mask.
- Masks should be put on when the HCW is at a short distance from a patient (1 meter).
- P2 respirator mask is not required.

B. Placement of patients on droplet precautions

- Single-patient room is ideal
- When single-patient rooms are in short supply
- Priority is given to patients who have excessive cough and sputum production for single-patient room placement
- Place together in the same room (cohort) patients who are infected with the same pathogen and are suitable roommates

• If it becomes necessary to place patients who require droplet precautions in a room with a patient who does not have the same infection.

  - Ensure that patients are physically separated (> 1metre apart) from each other and draw the privacy curtain between beds to minimize opportunities for close contact
  - Avoid placing patients on droplet precautions in the same room with patients who have conditions that may increase the risk of adverse outcomes (e.g. immunocompromised patient , cystic fibrosis, cardiac conditions or muscular dystrophy)

C. Transfer patients on droplet precautions

- Ask the patient to wear a mask while they are being transferred and to follow respiratory hygiene and cough etiquette

Steps in respiratory hygiene and cough etiquette
Anyone with signs and symptoms of a respiratory infection. regardless of the cause. should follow or be instructed to follow respiratory hygiene and cough etiquette as follows: • Cover the nose/mouth with disposable single-use tissues when coughing. sneezing. wiping and blowing noses • Dispose of tissues in the nearest waste receptacle or bin after use. • If no tissues are available, cough or sneeze into the inner elbow rather than the hand. • Practice hand hygiene after contact with respiratory secretions and contaminated objects materials. • Keep contaminated hands away from the mucous membranes of the eyes and nose.
In high risk OPDs such as pulmonary medicine OPD • Give mask to patients with cough and make separate queue away from the general queue. • Sign board indicating how to follow • Enough mask, tissue paper, hand rub and BMW bins • Sputum collection should be done in open space or in a well ventilated room

AIRBORNE PRECAUTIONS

1. **Why are airborne precautions important?**
   - Airborne precautions prevent transmission of microorganisms that remain infectious over time and distance when suspended in the air
   - Agents include measles (rubeola). chickenpox (Varicella) and *M.tuberculosis*
2. **How should airborne precautions he applied?**

   The key aspects of applying, airborne precautions relate to:

   A. Personal protective equipment
      - Wear a correctly fitted P2 respirator (e.g. N95 mask) when entering the patient-care area.
      - Gloves and gown may be used as per standard precaution

   B. Patient placement
      - Single room is advisable, preferably negative pressure room.
      - Ask patients to wear a surgical mask if he is with other patients in a room
      - Door to the room should remain closed.
      - Only staff and visitors who are immune to the specific infectious agent should enter the room. if possible,

   C. Transfer of patients
      - Limit transfer as much as possible,
      - Patient should wear a correctly fitted surgical mask.
      - Should follow respiratory hygiene and cough etiquette
      - Any associated skin lesions with the condition should be covered.

Table: Application of standard and transmission based precautions.

Type	Example	Single room or cohort	Gloves	Gown	Mask	Eye protection	Handling of equipment	Visitors
Standard	Should be followed: all patients All blood/fluid All sharps Irrespective of their infection status	Not required	As required	If soiling likely	Wear surgical mask during procedures likely to generate splash from blood and body fluids.	As required	Reprocess before reuse on next patient	No additional precautions.

Contact	MDROs C.difficile Diarrheal pathogens Highly contagious skin infections.	Essential	Essential	Essential	Surgical mask- required if infectious agent is also transmitted by droplet.	As required	Single use or reprocess before reuse on next patient.	Same precautions as staff.
Droplet	RSV Mycoplasma Parainfluenza Pertussis Plague and Meningococcus	Essential	As required	If soiling likely	Surgical mask is essential	As required	Same as contact	Restrict visitor numbers and precautions same as for staff.
Airborne	Pulmonary TB, Chicken pox, Measles, SARS.	Essential (negative pressure)	As required	If soiling likely	N95 respirator essential.	As required	Same as contact	Restrict visitor numbers and precautions same as for staff.

*Gloves are used when likely to touch blood, body fluids and contaminated items

**Eye protection is required during procedures likely to generate contamination with aerosols.

Table: type of precautions for specific infections and conditions.

Disease	**Agents**	**Precautions required (Over and above standard precautions)**	**Comments**
1) Diarrhoea			
Enteric pathogens	*Vibrio,E.coli,salmonella, Campylobacter, shigella, C.difficile, rota virus, norovirus* and others.	Standard and contact precautions (pediatrics and adult)	C.difficile and Rota virus needs contact precautions, others need standard precautions.
2) Meningitis			

	Neisseria meningitides *H.influenzae*	Droplet precautions for first 24 hrs of antimicrobial therapy mask and face protection is needed for intubation.	
	Enterovirus	Contact precaution for infants and children	
	M.tuberculosis	Airborne precautions needed for pulmonary infiltrate, airborne precautions plus contact precautions if potentially infectious draining body fluid present.	
3) Rash or exanthems generalized			
Petechial/ecchymotic with fever	*Neisseria meningitides*	Droplet precautions for first 24 hrs of antimicrobial therapy	
If a travel history to a area with viral hemorrhagic fever outbreak is there	Ebola, Lassa. Marburg viruses	Droplet precaution plus contact precautions, face/eye protection	During likely blood exposure emphasize sharps safety and barrier precautions
Vesicular rash	Varicella –zoster, herpes simplex ,Variola,Vaccinia	Airborne plus contact precautions	Contact precautions only, if herpes simplex, localized zoster in an immunocompromised host or vaccinia virus most likely
Maculopapular with cough, coryza and fever	Measles,parvo virus ,rubella	Airborne precautions Droplet precautions	If measles ruled out, only droplet precautions
4) Respiratory infections			
Sore throat	*S. pyogenes* *C.diphtheriae*	Droplet precautions	
Common cold	Rhinovirus	Droplet precautions	
Cough/fever/ pulmonary infiltrates	*M.tuberculosis* Respiratory viruses *S.pneumoniae,S.aureus,H.influenza,Mycoplasma,*Pertussis,Pneumon	Airborne precautions plus contact precautions	If tuberculosis is unlikely or there are negative pressure rooms or respirators

	ic plague		unavailable ,use droplet prewcautions instead of airborne precautions
Cough/fever/ pulmonary infiltrate history of recent travel (10-21 days) to countries with active out breaks of SARS, avian influenza	*M. tuberculosis* Severe SARS – Co V Avian influenza	Airborne plus contact precautions plus eye protection	If SARS and tuberculosis unlikely use droplet precautions instead of airborne precautions
Respiratory infection particularly bronchiolitis and pneumonia	RSV Para influenza virus Adenovirus Influenza Human metapneumo virus	Contact plus droplet precautions	Droplet precautions may be discontinued when adenovirus and influenza have been ruled out
5) Skin or wound infection			
Abscess or draining wound that cannot be covered	*Staphylococcus aureus*. Group A *streptococcus*	contact precautions	Add droplet precautions for first 24 hrs of appropriate antimicrobial therapy if invasive group A streptococcal disease is suspected
Impetigo	*S. aureus*	contact precautions	
Furunculosis	*S. aureus*	Infant/children – contact	
Scalded skin syndrome	*S. aureus*	contact precautions	
Pressure ulcer infected		contact precautions	
6) Sexually transmitted diseases			
Genital erosions, ulcerations ,discharge	*N.gonorrhoeae*, Syphilis,Trichomoniasis	Standard precautions	
7) Blood borne infections			
Fever, myalgia or jaundice or any other signs suggestive of blood borne diseases	Hepatitis B,C,D HIV Dengue fever	Standard precautions	Immunize and test all HCWs for hepatitis B,Occupational exposure protocol for blood borne viruses , post

			exposure prophylaxis if indicated
8) Conjunctivitis			
Conjunctival congestion discharge and other signs	Chlamydia trachomatis, Acute bacterial, Gonococcal, Acute viral hemorrhagic conjunctivitis	Standard precautions Contact precautions for acute viral hemorrhagic conjunctivitis	
9) MDROs (multi drug resistant organisms)			
Isolated MDROs from clinical specimens	Infection or colonization (e.g.MRSA,VRE,VISA/VRSA,ESBLs, Resistant S.pneumoniae	contact precautions	contact precautions recommended in settings with evidence of ongoing transmission or wounds that cannot be contained by dressings
10) Fungal diseases			
	Tinea, Aspergillosis,*Candida*	Standard precautions	
11) Miscellaneous			
	Leprosy	Standard precautions	
	Leptospirosis	Standard precautions	Person to person transmission is rare
	Pertussis	Droplet precautions	
	Rabies	Standard precautions Person to person transmission is rare if patient bites another person wash exposed area thoroughly and administer post exposure prophylaxis	
	Rickettsial fever	Standard precautions	
	Tetanus	Standard precautions	
	Typhoid	Standard precautions	

	Congenital rubella	Contact precaution	
	Pediculosis	Head lice contact, others – standard	
	Scabies	Contact	
	Polio	contact precautions	
	Extra pulmonary TB with draining lesion	Airborne and contact	

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Clostridium difficile infection:

Introduction

Clostridium difficile is an anaerobic, Gram-positive bacterium associated with pseudomembranous enterocolitis(PMC).

C.difficile has now become the most frequent cause of hospital-acquired diarrhoea especially in west because of emergence of the 027 hypervirulent epidemic strain.

RISK FACTORS

1. Exposure to especially high-risk antibiotics(3rd-generation cephalosporins, Clindamycin and quinolones)
2. Suppression of normal flora (conversion of primary bile salts to secondary bile salts is inhibited, secondary bile salts usually resists the germination of spores)
3. Advanced age (>65 years)
4. Immunosuppression (malignancy, defects in phagocytic and humoral host defence)
5. Prolonged hospital stay
6. Gastric acid suppressant medications
7. Use of electronic rectal thermometer
8. Inflammatory bowel disease
9. Exposure to hyper virulent 027 strain of C. difficile.

10. Gastrointestinal and transplant surgery
11. Enteral (post-pyloric) tube-feeding(rich in amino acids good medium for C.difficile growth)

PATHOGENESIS

C.difficile spores spread via the faecal oral route - The spores resist the acidity of the stomach → germinate into the vegetative form in the small intestine →vegetative forms colonize on the mucosa through surface proteins (adhesins) →C. Difficile toxins (A and B) came damage to enterocytes →results in cytoskeletal changes and the release of fluids and inflammatory products leading to colitis, pseudomembranous colitis (PMC), and profuse watery diarrhoea.

Hypervirulent epidemic (BI/NAPI/027) toxin type III) strain produce 20-fold higher concentrations of toxin A and toxin B leading to community acquired CDI in some population with associated risk factors such as increased PM usage.

CLINICAL FEATURES

- CM can run the gamut from asymptomatic colonization to severe

  PMC, toxic megacolon, and death.

- Mild disease: characterized by diarrhea in the absence of colitis
- Moderate disease: diarrhea with evidence of colitis
- Severe disease: Colitis with elevated temperature reaching 40°C,

  PMC and hypoalbuminemia

- Fulminant disease: severe abdominal pain, profuse diarrhea, or sometimes no diarrhea, toxic. megacolon.

Laboratory diagnosis:

Type of Test	Sensitivity	Specificity	Comment
Stool culture for *C. difficik* CCFA (Cycloserine Cefoxitin Fructose Agar) yellow colonies	++++	+++	Most sensitive test Less specific if not toxigenic Turnaround time too slow
Cell culture cytotoxin neutralization may	+++	++++	Highly specific but not as sensitive as stool culture Slow turnaround time
Toxin A or toxins A and B in	++ to +++	+++	Rapid results, less TAT

stool (EIA, ICT or latex agglutination)			but not as sensitive as stool culture or cell culture cytotoxin lest
C difficile common antigen in stool (glutamate dehydrogenase) (FAA, ICT or latex agglutination)	+++ to ++++	+++	Rapid result ,less TAT GDH found in both toxigenic and non toxigenic strains More sensitive and less specific than EIA for toxins
GDH and toxin in stool (EIA ,ICT or Latex agglutination)	+++ to ++++	++++	Rapid result ,less TAT sensitivity same as GDH , specificity increases
PCR for C.difficile toxin B gene in stool	++++	++++	Detects toxigenic C.difficile Less TAT More sensitive than EIA for toxin testing and at least a specific
Colonoscopy or sigmoidoscopy	+	++++	Highly specific if pseudomembranes are seen Sensitivity – very low

Note: ++++,> 90%;+++,71 – 90%;++,51-70%; +,50%

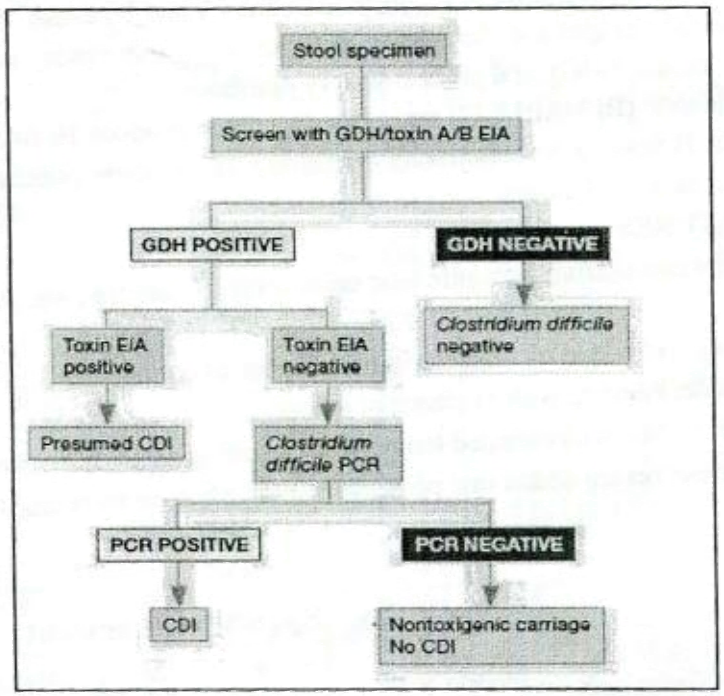

Figure-1: Two-step and Three-step Algorithms for Diagnosing *Clostridium difficile* Infection

PREVENTION STRATEGIES

Implementation of C difficile care bundle

I. Stop antibiotic if possible or change to low-risk narrow-spectrum agents.

2. Early diagnosis to identify cases and start treatment to control symptoms

3. Prompt isolation of patients as soon as possible in a single mom with en suite toilet

4, Implement infection control precautions

5. Clean and disinfect environment

6. Decontaminate/sterilize patient care items/equipment

Infection control measures

1. Strict hand washing with soap and water before and after contact with patients and environmental surfaces is the most effective

2. Use chlorhexidine 4% hand wash as alcohol hand disinfectants are not effective against C. difficile spores.

3. Transfer of patients between wards/units should be restricted unless considered essential.

4. Use of non-sterile single-use gloves and a plastic apron for patient care and hands arc washed after removing gloves.

5. Environment and other soiled areas must be thoroughly and frequently cleaned and then disinfected using a I% of freshly prepared hypochlorite solution.

6. Separate cleaning equipment must be reserved for cleaning the environment

7. Patients may remain colonized for long time. So if patient is transferred, then the subsequent hospital must be **informed.**

Management

•Discontinuation of the precipitating antibiotics

•Avoid antiperistalatic medication like opiates which results in retention of toxin

•Rehydration of patient

•Oral Metronidazole (500 mg p.o tid for 10 day) - mild to moderate disease

•Oral vancomycin (125 mg p.o qid for 10 days) - serious CDI

•Combination therapy with enteral vancomycin & Intravenous metronidazole in cases of ileus or toxic megacolon,

•Fidaxomicin- it is a macrolide antibiotic (200 mg p.o bid for 10 days). It can be used in highest risk for relapse.

•Intravenous immunoglobulin (150-400 mg/kg) passively provide antibodies to neutralize the C. difficile toxins, primarily toxin A

•Fecal transplant- it involves replenishing of the gut flora with donated feces from a screened healthy donor.

Why CDI is less common and severe in India:

Though not fully understood, possible contributory factors are

•predominantly vegetarian diet among Indians

•Over the counter supply and frequent use of metronidazole

•Non adherence to complete course of antibiotics

•A robust anamnestic antibody response due to repeated infections and

•Perhaps the virulent, more toxigenic strains may not be common in our country.

However, CDI's in India have always been found when looked for. It is much more likely that more cases will come to light as the toxin assays and more sophisticated methods of diagnosis are used on a larger scale.

CDI LAB-ID EVENT SURVEILLANCE FOR *C.DIFFC1LE*

C. difficile testing in the laboratory is performed routinely only on unformed (i.e. conforming to the shape of the container) stool samples.

•C. difficile Lab identification (LablD) events may be monitored from all available inpatient locations as well as all available affiliated outpatient locations

•Surveillance will NOT be performed in NICU, SCN, babies in LDRP. Well-baby nurseries or well-baby clinics.

CDI-positive laboratory assay:	Any laboratory test positive for *C.difficile* toxin A and B (PCR, EIA, 1CT, Culture) performed on unformed stool
Duplicate *C. difficile*-positive test:	Any positive laboratory test for *C.difficile* toxin A and for B from the same patient and location, following a previous *C.difficile* toxin-positive laboratory result within the past two weeks [14 days]
Recurrent CDI LabID Event:	Any CDI LabID Event from a specimen obtained > 14 days (2 weeks) and ≤ 56 days (8 weeks) after the most recent CDI LablD Event for that patient.
Incident CDI LablD Event:	Any CDI LabID Event from a specimen obtained > 56 days (8 weeks) after the most recent CDI LabID Event (or with no previous CDI LablD Event documented) for that patient.
Community-Onset CDI (CO):	LabID Event collected in an outpatient location or an inpatient location <3 days after admission to the facility.
Community-Onset Healthcare Facility-Associated	CO LablD Event collected from a patient who was discharged from the facility ≤4 weeks prior to current date of stool specimen collection. Data from outpatient locations (e.g._, outpatient encounters) are not included in this definition.

Healthcare Facility-Onset:	LablD Event collected >3 days after admission to the facility (i.e., on or after day 4).

*The date of specimen collection is considered Day 1.

References:

1. National Healthcare Safety Network (NHSN) (Internet).Centers for Disease Control and Prevention; [cited November 21, 2016]. Available from: https://www.cdc.gov/nhsn/

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Policy on safe injection and infusion practices

Purpose:

1. To ensure the safety of injections and related practices
2. To prevent any avoidable risk to the providers
3. To prevent cross infection

Scope: The following are applicable to hospital**.**

- To make sure that entire process of administering an injection is safe, the equipment used, techniques applied and process involved should be in a most safe and hygienic manner.
- Hand hygiene surveillance and monitoring
- Conduct training on safe injection and infusion practices
- Develop action plan and function accordingly.

Safe Injection and Infusion Practices

A safe injection, lancet procedure or intravenous device insertion is one that:

A. Does not harm the recipient.

B. Does not expose the provider to any avoidable risk.

C. Does not result in any waste that is dangerous for other people.

Purpose:

The purpose of SAFE Injection and Infusion Practices is to promote implementation of safe practices associated with the following medical procedures:

- ¬ Intradermal, subcutaneous and intramuscular needle injections
- ¬ Intravenous infusions and injections
- ¬ Lancet procedures.

General safety practices

This section describes the following practices that are recommended to ensure the safety of injections and related practices:

- ¬ Hand hygiene
- ¬ Gloves where appropriate
- ¬ Other single-use personal protective equipment
- ¬ Skin preparation and disinfection

A. Hand hygiene- Perform hand hygiene **BEFORE:**

- ¬ Starting an injection session (i.e. preparing injection and giving injections)
- ¬ Coming into direct contact with patients for health-care related procedures
- ¬ Putting on gloves (first make sure hands are dry).

A. Hand hygiene- Perform hand hygiene **AFTER**:

- ¬ An injection session
- ¬ Any direct contact with patients
- ¬ Removing gloves.

Skin Preparation And Disinfection

To disinfect the skin, use the following steps

1. Apply a 60–70% alcohol-based solution (isopropyl alcohol or ethanol) on a single-use swab or cotton wool ball. DO NOT use methanol or methyl-alcohol as these are not safe for human use.

2. Wipe the area from the centre of the injection site working outwards, without going over the same area.

3. Apply the solution for 30 seconds then allow it to dry completely.

Injection Devices :The management of SVIMS shall ensure that an adequate supply of single-use devices is available, to allow providers to use a new device for each procedure.

G. Practical Guidance On Use Of Injection Devices

When using a sterile single-use device

a) Use a new device for each procedure, including for the reconstitution of a unit of medication or vaccine;

b) Inspect the packaging of the device to ensure that the protective barrier has not been reached;

c) Discard the device if the package has been punctured, torn or damaged by exposure to moisture, or if the expiry date has passed.

H. Medication

I. When giving medication:

a) NOT use a single loaded syringe to administer medication to several patients (i.e.ensure one needle, one syringe, one patient!)

b) DO NOT change the needle in order to reuse the syringe

c) DO NOT use the same mixing syringe to reconstitute several vials

d) DO NOT combine leftover medications for later use.

Single-dose vials – Whenever possible, use a single-dose vial for each patient, to reduce cross contamination between patients.

Multi dose vials – Only use multi dose vials if there is no alternative.

i. Open only one vial of a particular medication at a time in each patient-care area.

ii. If possible, keep one multi dose vial for each patient, and store it with the patient's name on the vial in a separate treatment or medication room.

iii. DO NOT store multi dose vials in the open ward, where they could be contaminated with spray or spatter.

Discard a multi dose vial:

i. If sterility of content is compromised

ii. If the expiry date or time has passed (even if the vial contains antimicrobial preservatives)

iii. If it has not been properly stored after opening

iv. Within 24 hours of opening, or after the time recommended by the manufacturer, if the vial does not contain antimicrobial preservatives

v. If found to be undated, improperly stored, inadvertently contaminated or perceived to be contaminated, regardless of expiry date.

Preparing injections

Injections should be prepared in a designated clean area where contamination by blood and body fluids is unlikely.

Practical guidance on preparing injections

Three steps must be followed when preparing injections.

- Keep the injection preparation area free of clutter so all surfaces can be easily cleaned.
- Before starting the injection session, and whenever there is contamination with blood or body fluids, clean the preparation surfaces with 70% alcohol (isopropyl alcohol or ethanol) and allow drying.
- Assemble all equipment needed for the injection
  - Sterile single-use needles and syringes,
  - Reconstitution solution such as sterile water or specific diluents,
  - Alcohol swab or cotton wool,
  - Sharps container.

Labelling

After reconstitution of a multi dose vial, label the final medication container with

- Date and time of preparation
- Final concentration
- Expiry date and time after reconstitution
- Name and signature of the person reconstituting the drug.

For multi dose medications that DO NOT requires reconstitution, add a label with:

- Date and time of first piercing the vial
- Name and signature of the person first piercing the vial.

Administering Injections

An aseptic technique should be followed for all injections.

Practical guidance on administering injections

General

When administering an injection:

- Check the drug chart or prescription for the medication and the corresponding patient's name and dosage
- Perform hand hygiene
- Wipe the top of the vial with 60–70% alcohol using a swab or cotton-wool ball
- Open the package in front of the patient to reassure them that the syringe and needle have not been used previously
- Using a sterile syringe and needle, withdraw the medication from the ampoule or vial.

Reconstitution

- If reconstitution using a sterile syringe and needle is necessary, withdraw the reconstitution solution from the ampoule or vial, insert the needle into the rubber septum in the single or multi dose vial and inject the necessary amount of reconstitution fluid.
- Mix the contents of the vial thoroughly until all visible particles have dissolved.
- After reconstituting the contents of a multi dose vial, remove the needle and syringe and discard them immediately as a single unit into a sharps container.

Delay in administration

- If the dose cannot be administered immediately for any reason, cover the needle with the cap using a one hand scoop technique.
- Store the device safely in a dry kidney dish or similar container.

Important points

- DO NOT allow the needle to touch any contaminated surface.
- DO NOT reuse a syringe, even if the needle is changed.
- DO NOT touch the diaphragm after disinfection with the 60–70% alcohol till it dries up (isopropyl alcohol or ethanol).
- DO NOT enter several multi dose vials with the same needle and syringe.
- DO NOT re-enter a vial with a needle or syringe used on a patient if that vial will be used to Withdraw medication again (whether it is for the same patient or for another patient)

<u>Prevention of sharps injuries to health workers</u>

Use of best practices can help to prevent sharps injuries to health workers

Practical guidance on prevention of sharps injuries

To avoid sharps injuries:

1. Ensure that the patient is adequately prepared for the procedure

2. Do not bend, break, manipulate or manually remove needles before disposal

3. Avoid recapping needles, but if a needle must be recapped, use a single-handed scoop technique

4. Discard used sharps and glass ampoules immediately after use in the location where they were used, disposing them into a robust sharps container that is leak and puncture resistant

5. Place the sharps container within arm's reach (preferably in a secured area) to allow for easy disposal of sharps

6. Seal and replace sharps container when the container is three quarters full.

B. Staff at SVIMS, who are in direct contact with patients, shall wear non-sterile, well-fitting latex or latex-free gloves when coming into contact with blood or blood product. Indications for glove use in injection practice are

Key Elements	**Indications**	**Precautions**
Glove use	Wear non-sterile, well-fitting, single-use gloves: •when there is a likelihood of coming into direct contact with a patient's blood or other potentially infectious materials (e.g. body fluids, moist body substances and saliva [in dental procedures]), mucous membranes and nonintact skin •when performing venipuncture or venous access injections, because of the potential for blood exposure at the puncture site •if the health worker's skin is NOT intact (e.g. through eczema, or cracked or dry skin)	When undertaking injections, **DO NOT** use gloves: •for routine Intradermal, subcutaneous and intramuscular injections •if the health worker's skin is intact •if the patient's skin is intact. Gloves **DO NOT** provide Protection against needle-stick or other puncture wounds caused by sharp objects. Needles, scalpels and other sharps should be handled with extreme caution.

Other Single-Use Personal Protective Equipment

- Masks, eye protection and other protective clothing ARE NOT indicated for the injection procedures unless exposure to blood splashes is expected.
- When using single-use personal protective equipment, dispose of the equipment immediately after use.

Policy on cleaning & disinfection

Purpose:

This policy aims

1. To guide hospital employees in the appropriate measures to reduce infection from inanimate objects using the processes of disinfection and sterilization.

Scope:

- This policy applies and extends to cover all healthcare professionals in SVIMS hospital wherever they work.
- Conduct training.
- Develop action plan and function accordingly.

This policy and procedure will be applied fairly and consistently to all employees regardless of their protected characteristics as defined by the Equality Act 2010 namely, age, disability, gender reassignment, race, religion or belief, sex, sexual orientation, marriage or civil partnership, pregnancy and maternity, length of service, whether full or part□time or employed under a permanent or a fixed□term contract, irrespective of job role or seniority within the organisation.

Where an employee has difficulty in communicating, whether verbally or in writing, arrangements will be put in place as necessary to ensure that this policy and associated processes to be followed are understood and that the employee is not disadvantaged during application of this policy.

In line with the Equality Act 2010, the SVIMS will make reasonable adjustments to the processes to be followed where not doing so would disadvantage an employee with a disability during the application of this policy.

<u>Receipt of used material for processing</u>

All items should be collected and distributed twice a day, if necessary whenever required.

When the items are collected back from various patient care areas arrives to the reception area. The quantity of each item that is collected is recorded in a book and a receipt is to be issued stating the number of items, signature of the person who received.

The common items handled by the CSSD store are syringes and needles, Procedure sets which includes Lumbar puncture, sternal puncture, venesection, paracentesis, aspiration,

catheterization, tracheostomy, suturing, dressing, biopsy, incision and drainage, OT instruments, OT linen etc

CLEANING, DISINFECTION

1. Proper method of Cleaning

Cleaning may be done manually or using mechanical cleaning machines (e.g. washer-disinfector, ultrasonic washer, washer-sterilizer) after gross soil has been removed.

Automated machines may increase productivity, improve cleaning effectiveness and decrease staff exposure to blood and body fluids.

Manual cleaning may be required for delicate or intricate items.

The equipment/device manufacturer's cleaning instructions shall be followed, including specifications for detergent type, water temperature and cleaning methods.

The following procedures are included in the cleaning process:

a) *Physical Removal of Organic Materials*

i. Completely submerge immersible items during the cleaning process to minimize aerosolization of microorganisms and assist in cleaning.
ii. Minimize the production of aerosols when cleaning non-immersible equipment/devices
iii. Remove gross soil using tools such as brushes and cloths

b) Manual Cleaning

i. Any brushing required should be done under water
ii. Clean equipment/devices that have lumens with a brush, according to the manufacturer's instructions, then manually or mechanically flush with a detergent solution and rinse
iii. Check equipment/devices with lumens for obstructions and leakage

c) Mechanical Cleaning

Whenever possible, clean equipment/devices by mechanical means:

i. Any brushing required should be done underwater

ii. Use mechanical washers in accordance with the manufacturer's instructions
iii. Manually clean heavily soiled equipment/devices before mechanical cleaning
iv. Ensure that the equipment/device to be cleaned is compatible with the mechanical
v. Cleaning equipment and chemical solutions that are being used
vi. Ultrasonic washers are strongly recommended for any semi-critical or critical medical equipment/device that has joints, crevices, lumens or other areas that are difficult to clean

- The manufacturer's instructions must be followed for use and routine cleaning and maintenance of the ultrasonic washer
- Equipment/devices shall be completely immersed in the washing solution
- After cleaning, equipment/devices shall be rinsed thoroughly prior to further reprocessing
- The ultrasonic washing solution should be changed at least daily or more frequently if it becomes visibly soiled or if the manufacturer's instructions specify more frequent changes
- Washer-disinfectors are strongly recommended for medical equipment/devices that can withstand mechanical cleaning, to achieve the required exposure for cleaning and to reduce potential risk to personnel
- The manufacturer's instructions must be followed for the use and routine maintenance, cleaning and calibration of the washer-disinfector
- Washer-disinfectors may be used for low-level disinfection
- Washer-disinfectors are not to be used for high-level disinfection

<u>Cleaning Protocols</u>

1. Mopping plan

- Mopping plan means cleaning done from clean area to unclean area.
- It gives special information to cleaning staff about priority of cleaning.
- Mopping plan contains four categories

a) Immuno compromised patient's room

b) Room of the patient with clean case -Clean room

c) General

d) Infected

If there is a patient with communicable disease that room should be cleaned in the last, irrespective of plan (Direction will be given by the Head nurse/ Sr. Staff Nurse on duty Housekeeping supervisor/ HIC Nurse)

2. Environment:-

- ϖ Clean the floors with a disinfectant thrice a day.
- ϖ Clean with Lysol solution 3 times a day
- ϖ Wash the floors with soap & water and disinfecting solution (Lysol) using scrubbing machine once in a week.

Do not carry out any cleaning activities while

1. Sterile supplies are being handled.

2. Sterile procedures are in progress.

a. Use 1 % Sodium Hypochlorite solution to clean environment surfaces if contamination with blood and body fluids occur.

b. Use 1 % Sodium Hypochlorite solution for 30 min for disinfecting mops used for cleaning blood.

c. Detach the pads and brushes of scrubbing machine after each use, clean thoroughly and dry.

d. Clean the walls and ceilings weekly and on transfer / discharge/ death of a patient.

3. High Risk Areas:-

a. Floors are cleaned with prescribed disinfectant five times a day with 2% Lysol.

b. Ventilator parts are cleaned with prescribed disinfectant.

c. All equipment including monitor are cleaned with prescribed disinfectant spray.

d. Some plastic items like Ambu bag, ventilator tubing, O_2mask, Nebulization set are sterilized by formalin gas (generally ETO sterilization recommended - implement the same)

e. Change the HEPA filter (ventilator) every 72 hours.

f. Keep a disinfectant hand rub solution (Sterilium) in each bed side.

g. Keep separate stethoscope, BP always ready to use with a standby.

h. Damp dust bed frames, railings, I/V stands, lockers etc. daily with prescribed disinfectant.

i. Floor cleaning done four times in a day with prescribed disinfectant.

j. Cover the mattresses and pillows with water proof covers.

k. Use disposable plastic sheets / Mackintosh to protect the bed linen.

l. Disinfect the patient's unit with prescribed disinfectant solution after the transfer / discharge / death.

m. Check the expiry date of CSSD items every day.

4. Wards:-

a. Damp dust the bed frames, railings, I/V stands, lockers etc. daily with prescribed disinfectant (Lysol)

b. Floor cleaning done three times a day from clean area to unclean area

c. Cover the mattresses and pillows with water proof cover.

d. Use disposable plastic sheets or mackintosh to protect the bed linen.

e. Disinfect the unit with prescribed disinfectant after the discharge/ death of a patient.

f. Fumigate the room after the transfer/ discharge/ death of an infected patient with Lysol.

d) Care of Cleaning Tools

i. Inspect brushes and other cleaning equipment for damage after each use, and discard if necessary
ii. Clean, disinfect, dry and store tools used to assist in cleaning (e.g. brushes, cloths).

e) Rinsing

Rinsing following cleaning is necessary, as residual detergent may neutralize the disinfectant

i. Rinse all equipment/devices thoroughly after cleaning with water to remove residues which might react with the disinfectant sterilant

ii. Perform the final rinse for equipment/devices containing lumens with commercially prepared sterile, pyrogen-free water (note: distilled water is not necessarily sterile or pyrogen-free).

f) Drying

Drying is an important step that prevents dilution of chemical disinfectants which may render them ineffective and prevents microbial growth

i. Follow the manufacturer's instructions for drying of the equipment/device
ii. Equipment/devices may be air-dried or dried by hand with a clean, lint-free towel
iii. Dry lumens with compressed air that has been filtered and dried
iv. Dry stainless steel equipment/devices immediately after rinsing to prevent spotting.

2. Post-Cleaning

Once medical equipment/devices have been reprocessed, there must be a process to ensure that they can be differentiated from equipment/devices which have not been reprocessed. Sterilized items may be identified using external chemical indicators (CIs), such as autoclave tape, which changes color during sterilization. Equipment/devices which receive high-level disinfection should also be labeled, tagged or color-coded to indicate that they have been reprocessed. The following procedures must be included following the cleaning process.

3. Inspection and Assembling:

i. Visually inspect all equipment/devices once the cleaning process has been completed and prior to terminal disinfection/sterilization to ensure cleanliness and integrity of the equipment/device (e.g. cracks, defects, adhesive failures, missing parts)
ii. Repeat the cleaning of any item that is not clean
iii. Do not reassemble equipment/device prior to disinfection/sterilization
iv. If the equipment/device manufacturer's instructions specify reassembly at this stage in the reprocessing, it shall take place in a clean area and be performed in accordance with the manufacturer's instructions.
v. Damaged item should be condemned, repairable should be repaired and then assembled.

Lubrication

i. Follow the manufacturer's guidelines for lubrication
ii. Equipment/devices requiring lubrication shall be lubricated prior to sterilization
iii. Lubricants shall be compatible with the device and with the sterilization process
iv. Discard lubricants on expiry date or when visibly soiled or contaminated

4. **Disinfection:**

Disinfection is a process where most microbes are removed from defined object or surface, except spores. Disinfectants can be classified according to their ability to destroy different categories of micro-organisms:

- High Level disinfectants: 2%,Glutraldehyde, Ethylene Oxide
- Intermediate Level disinfectant: Alcohols, chlorine compounds, hydrogen Peroxide, chlorhexidine,
- Low level disinfectants : Benzalkonium chloride, some soaps

GENERAL GUIDELINES FOR DISINFECTION:

1. **Critical instruments/equipment** (that is those penetrating skin or mucous membrane) should undergo sterilization before and after use. e.g. surgical instruments.

2. Semi-critical instruments /equipments (that are those in contact with intact mucous membrane without penetration) should undergo high level disinfection before use and intermediate level disinfection after use. e.g. endotracheal tubes.

3. Non-critical instruments /equipments (that are those in contact with intact skin and no contact with mucous membrane) require only intermediate or low level disinfection before and after use. e.g. ECG electrodes

5.Wrapping/Packaging:

i. Equipment/devices that are to be sterilized require wrapping prior to sterilization (except for intermediate use steam sterilization)
ii. Wrapping should be done with linen/ draper after drying and assembling.
iii. Container and materials used for wrapping shall be prepared in a manner that will allow adequate air removal, steam penetration and evacuation to all surfaces.
iv. Seal either manually or using a machine before sterilization

6.Labeling:

Done for identification

Date, contents, identification number, bar codes, initial of person who carried out sterilization, initial of packers are used

7.Issuing of items: Items issued must be documented in the register by name of the department supplied, date etc.

8.Procedure for outdated items

Items which have crossed the expiry date should be returned and new ones obtained.

9.Indexing of records

All documentation should be dated and signed by the person completing the documentation and/or verifying the test results.

Documentation of the sterilization process should include:

10.Package label:

a) Name of device (when necessary).
b) Initials of technician packaging the device.
c) Lot control information which includes a load or cycle number, sterilizer number, and the date of sterilization.
d) Detailed list of sterilizer load contents
e) Date, time, and results of all tests performed (for example, printout, Chemical Indicator, Biological Indicator, Bowie-Dick, leak test).

11.Packaging:

Packaging materials for steam sterilization should:

a. Be validated for steam sterilization.
b. Contain no toxic ingredients or dyes.
c. Be capable of withstanding high temperatures.
d. Allow air removal from packages and contents.
e. Permit sterile contact with the package contents.
f. Permit drying of the package and contents.
g. Prevent the entry of microbes, dust, and moisture during storage and handling.
h. Have a proven and tamper-proof seal.
i. Withstand normal handling and resist tearing or puncturing.

12.Unloading

Upon completion of the cycle, the operator responsible for unloading the sterilizer should:

Review the sterilizer printout for the following:

a. Correct sterilization parameters.
b. Cycle time and date.
c. Cycle number matches the lot control label for the load.

d. Verify and initial that the correct cycle parameters have been met.

e. Examine the load items for:

- Any visible signs of moisture.
- Any signs of compromised packaging integrity.

Printed records of each cycle parameter (that is, temperature, time) should be retained in accordance with the healthcare settings requirements.

Load Cool-Down

Upon removal of the sterilized load the operator should:

a. Visually verify the results of the external chemical indicators.

b. Allow the load to cool to room temperature (the amount of time for cooling depends on the devices that have been sterilized).

c. Ensure cool down occurs in a traffic-free area without strong warm or cool air currents.

13. Maintenance of Sterile Storage

It is important to store sterilized instruments and supplies in a manner that maintains their aseptic conditions. Keep them in a dust –free, clean environment until use.

i. The sterile storage area should be a limited access area with a controlled temperature (may be as high as 24^{o}C) and relative humidity (30-60% in all works areas except sterile storage, where the relative humidity should not exceed 70%).

ii. The floors and walls should be constructed of materials capable of withstanding chemical agents used for cleaning or disinfecting. Ceilings and wall surfaces should be constructed of non-shedding materials.

iii. Hand hygiene facilities should be located in all personnel support areas and at all entrances to, and exits from, the decontamination area. Hand hygiene facilities should include:

- accessible hand washing sinks with hands-free controls, soap dispensers and paper towels; and/or
- Alcohol-based hand-rub (ABHR).

Basic steps in tank cleaning:

• **Step 1: The area surrounding the tank and top of the tank is cleaned**
• **Step 2: Tools used in tank cleaning process are disinfected**
• **Step 3: Water and sludge is drained out from the tank using a sludge pump**
• **Step 4: Manual scrubbing of the tank is done to remove the dirt, sediments, fungus & stains**
• **Step 5: Walls, ceiling and floor of the tank is washed using a high pressure jet**
• **Step 6: Vacuum cleaning is done to ensure that all the dirt is sucked out**
• **Step 7: Vacuumed tank is disinfected with anti-bacterial spray or liquid bleach**
• **Step 8: Tank is filled with water that is made to run through the taps to disinfect the water pipes**
• **Step 9: Water from the tank is drained through the taps and tank is left empty for drying**
• **Step 10: Tank is clean and ready to be filled with water for domestic use**

CLEANING AND DISINFECTING A WATER HOLDING TANK

Delivered water should be potable (safe for human consumption) and obtained from an approved source.

It is necessary to clean and disinfect your water holding tank(s) at least once a year or more often, if required. This is to remove algae (plant growth which produces bad tastes and odours), silt, and bacteria which may be harmful.

If the Water Holding Tank is:

*Accessible for Cleaning

1. Empty the tank.

2. Scrub or pressure washes the interior walls to remove dirt and grime.

3. Rinse out the tank.

4. Mix a solution of household bleach and water (1 tablespoon or 15 ml of bleach for every gallon of water).

5. Scrub or pressure wash the interior walls of the tank with this solution, and leave it sit for 2 hours.

6. After 2 hours, thoroughly rinse the tank with clean water. 7. Refill with potable water.

* Caution is to be taken when using a strong chlorine solution. A water holding tank is a confined space. Under no circumstances should you enter a confined space, unless taking the appropriate precautions

Not Accessible for Cleaning

1. Ensure the tank is full of water.

2. Add the required amount of household bleach (see table below to the water in your holding tank. If possible, mix the bleach and water.

3. To disinfect the plumbing lines and fixtures, turn the tap(s) on. Once you smell the chlorine odor at each outlet, close the tap.

4. Leave for 12 hours (generally done overnight). 5. Drain the water tank (but not into a septic tank). 6. Refill with potable water.

Dosage of Household Bleach (5% chlorine) required for the Cleaning and Disinfecting of Water Holding Tanks not Accessible for Cleaning				
Tank Size		Amount of Household Bleach to Obtain 50 ppm of Chlorine		
Litres	Imp. Gallons	mL	Imp. Ounces	Cups
277	**50**	**227**	**8**	**1**
455	**100**	**511**	**16**	**2**
909	**200**	**909**	**32**	**4**
1137	**250**	**1136(1.2L)**	**40**	**5**
2273	**500**	**2273 (2.3L)**	**80**	**10**
4546	**1000**	**4546 (4.5L)**	**160**	**20**
6819	**1500**	**6818 (6.8L)**	**240**	**30**
9092	**2000**	**9091(9.1L)**	**320**	**40**
11365	**2500**	**11340(11.5L)**	**400**	**50**

How to prepare a chlorine solution :

Where chlorine solution is not available in the market, one can make it by using a solution of bleaching powder, normally available in local community health posts.

• Place 40 gm (about 5 tea spoons) of bleaching powder in plastic mug and add some water to make a thick paste

• Add 1 liter of water and stir the solution thoroughly

• Put the solution aside for 5 minutes to settle. A clear chlorine solution will appear at the top with some residue settling at the bottom

• Carefully pour the clear chlorine solution to a colored plastic jar and seal tightly. Throw the residue in the drainage.

• The prepared chlorine solution is 1% chlorine solution. Store the solution in a dark place away from children.

How to use a chlorine solution:

• Three drops of 1% chlorine solution can treat 1 liter of drinking water.

• One liter of chlorine solution can treat 10,000 liters of water.

• After determining the volume of a water tank, the exact chlorine dose can be determined. For example: How much chlorine solution is required to treat 2,000 liters of water? For 10,000 liters of water – 1 L chlorine solution; For 1 L water – 1/10,000 L chlorine solution; and

For 2000 L water – 1/10,000 x 2,000 L = 0.2 L or 200 ml of chlorine solution is required

• The water will be safe to use 30 minutes after adding chlorine solution • Calculating the water tank volume

i. For a rectangular water tank

Volume of tank (V) = [Length (L) x Breadth (B) x Height (H) of tank] x 1000 L Example: Given that L=2 m; B=2 m & H=3 m V = L x B x H x 1000L = 2 x 2 x 3 x 1000 L

Therefore, Volume of the tank (V) = 12,000 L And to treat 12,000 L water – 1/10,000 x 12,000 L = 12 L of chlorine solution is required

ii. **For cylindrical water tank**

Volume of tank (V) = [π x r2 x Height (H) of tank] x 1000 L, Where "r" is the radius of the tank, which could be calculated by: diameter/2, & π = 22/7 Example: Given that r= 1 m; H=3 m V = (π x r2 x H) x 1000 L = 22/7 x 1 x 1 x 3 x 1000 L Therefore, volume of the tank (V) =

9428.5 L To treat 12,000 L water – 1/10,000 X 9428.5 L = 0.95 L or 950 ml of chlorine solution is required

Recommendations for RO Tank , loop, R.O membrane, Hemodialysis machines:

1. RO Membrane Disinfection

Note: The deionizer connections need to be removed completely and there should not be dead end in the loop.

1-a. Sodium Hypochlorite

The RO membrane should be removed from the membrane housing and the membrane housing and corresponding pipes should be disinfected with Sodium Hypochlorite (Dilution 1:25). 30 min. circulation and 30 minutes dwell time. Then flush out with fresh R.O water.

1-b. Puristeril (Peracetic Acid + Hydrogen Peroxide)

After loading the membrane in the membrane housing, disinfect the membrane and corresponding pipes with Puristeril (Dilution 1:20). 30 minutes circulation and 30 minutes dwell time and 15 minutes circulation. Then flush out with fresh (R.O) water.

2. RO Tank and Loop disinfection

2-a. Sodium Hypochlorite

Mix the Sodium Hypochlorite in the tank (Dilution 1:25). Circulate for entire loop for 30 minutes circulation, 30 minutes dwell time, 15 minutes circulation and flesh out with fresh R.O water.

2-b. Puristeril (Peracetic Acid + Hydrogen Peroxide)

Mix the Puristeril in the tank (Dilution 1:20). Circulate for entire loop for 30 minutes circulation, 30 minutes dwell time, 15 minutes circulation and flesh out with fresh R.O water.

Note: While doing the circulation of loop, disconnect all the machine and rinse the water inlet tubes with disinfectant from the loop and flush out with fresh R.O water after during the flushing of loop. Repeat this procedure for both Sodium Hypochlorite and Puristeril phases.

The above method should be followed for both RO systems.

Residual disinfection test must be carried out.

3. Machine disinfection

Please disinfect the machine with Sodium Hypochlorite (Front Supplied) and then with puristeril with dwell time of 30 minutes. Then flush out completely with endless rinse for 3 hours.

Please test the residual disinfection in both loop and machines before connecting the patient.

4. Things to be followed after disinfection

4-a. Samples to be taken from the following points using aseptic technique. 1. R.O Outlet 2. Tank outlet 3. First point in the loop 4. Middle point of the loop 5. End point of the loop for both the RO systems.

4-b. Samples to be taken for Endotoxin test. 1. Outlet of both RO and 2 points in the loop.

4-c. After each dialysis hot disinfection with citrosteril should be performed for all the machines.

Maintenance of Dialysis machine & RO System for SVIMS

Daily Maintenance:

1. Fill up & monitor daily RO maintenance protocol check list *
2. Beginning & In between treatment hot rinse only for HD machines
3. End of the day hot disinfection with citrosteril, followed by hot rinse without cooling rinse.
4. Bicarbonate Canister to be changed every 2nd day& mixer need to be cleaned with bleach at the end of the day.

Weekly Maintenance:

1. Clean with 4% formalin for 12 hrs dwell time all the machine along with RO loop.
2. After Cleaning, CFU & EU to be sampled from RO plant, Loop (starting, mid& end) and all machines.(only after 24 hrs of cleaning, and for machine after 30 min of T1 test passed)
3. Pore 100 ml of bleach 1% to all drain point of the machines
4. Hardness & chloramines to be monitored from the pretreatment plant.
5. All the machine to be tested for correct electrolytes and documented

Monthly Maintenance:

1. If RO culture report above action level RO membrane to be cleaned with Puristeril offline.
2. Front supply bleach to be given for all HD machines

Annually:

1. Make sure that all the machines PPM should be done with biomedical engineer.
2. Yearly change 0.2 µ filter.

Notes: This protocol may be reversed after 3 months monitoring

- Please cover all pipe line of the loop which is exposing to sunlight.
- Do not modify the RO loop without consulting with Bio Medical department of the hospital.
- Make sure that all the brass connecter & old loop parts disconnected from the new RO loop.
- Remove post treatment mixed bed vessel from all RO plants.
- Online TDS or conductivity monitor for RO plant to be installed.
- We also recommend endotoxin filter for all machine and online Bicarb preparation from a USP grade bicarbonate.

Antibiotic policy and rational use of antimicrobial agents

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A.

Sl. Order	Particulars
A	Purpose
B	Scope
C	Guideline for Antibiotic Treatment and Prophylaxis

Purpose:

- Improve patient care by promoting the best practice in antibiotic prophylaxis and therapy.
- Make better use of resources by using cheaper drugs where possible.
- Retard the emergence and spread of multiple antibiotic – resistant bacteria.
- Improve education of doctors by providing guidelines for appropriate therapy.
- Eliminate the use of unnecessary or ineffective antibiotics and restrict the use of expensive or reserve drugs.

B. Scope: Hospital Wide

- Consider whether or not the patient actually requires an antibiotic.
- Avoid treating colonized patients who are not actually infected.
- In general do not change antibiotic therapy if the clinical condition is improving.
- If there is no clinical response within 72 hours, the clinical diagnosis, the choice of antibiotic and/or the possibility of a secondary infection should be reconsidered.
- Give the antibiotic for the minimum length of time that is effective.
- Review the duration of antibiotic therapy after 5 days.
- For surgical prophylaxis start the antibiotic one hour before induction of anesthesia and in the case of surgery more than 4 hours another dose of antibiotic can be given.

- Use catheters only when essential; remove when no longer essential.
- Target the pathogen – obtain cultures from the patient; target empiric therapy to likely pathogens; target definitive therapy to known pathogens.
- Isolate the pathogen – use standard infection control and isolation precautions
- Break the chain of contagion – KEEP YOUR HANDS CLEAN

ANTIMICROBIAL POLICY AND ANTIMICROBIAL STEWARDSHIP

Introduction

The annual antibiogram should be prepared by microbiology department in coordination with medical and surgical departments. Antibiotic susceptibility profile analyzed regularly and the common resistance patterns of the bacterial isolates to be reported and discussed in the HICC meetings and the antibiotic policy to be reviewed accordingly.

Antibiotic policy need to be prepared in consultation with respective clinical departments.

Antibiotic policy shall be prepared using following general principles:

1. Data is analyzed on a quarterly basis as per hospital records.

(a) Common etiological agents as per

(i) Site of infection

(ii) Age groups

(iii) Patient location – outdoor (OPD), indoor (wards & critical care areas)

(b) Antibiogram data as per

(i) Site of infection

(ii) Age groups

(iii) Patient location – outdoor (OPD), indoor (wards & critical care areas)

(c) Unusually resistant organisms to be confirmed and submitted for further characterization to National Centre for Disease Control (NCDC).

2. Standard treatment guidelines [categorization of patients as per age and Community acquired infections (CAI) / Health care associated infections (HCAI)]

(a) Guidelines for empirical antimicrobial therapy as per common clinical syndromes

(i) Adults & older children

1. Blood Stream Infections (BSI)

2. Meningitis

3. UTI

4. Pneumonia (a) Community Acquired Pneumonia (CAP) (b) Ventilator Associated Pneumonia (VAP)

5. GIT Infections

6. Conjunctivitis

7. Otitis Media

8. Tonsillitis / Pharyngitis

9. Skin and Soft Tissue Infection (SSTI)

10. Genital Infections

11. Osteomyelitis

(ii) Neonates (special conditions) 1. Sepsis 2. Meningitis

(iii) Infants & Small Children (special conditions) 1. Meningitis 2. Sepsis 3. Pneumonia

(b) Classification of Antimicrobials into Access, Watch and Reserve drugs as per WHO,2017.

(c) Chemoprophylaxis (i) Pre-operative antimicrobials (ii) Other invasive procedures (iii) Special high risk groups e.g. Prophylaxis for rheumatic fever, splenectomy patients, and Immuno-compromised patients

(d) Special clinical syndromes (e.g. STIs)

3. Prescription auditing

4. Review of surveillance data generated from antibiogram & prescription auditing.

5. Education and training for all infection control activities in collaboration with the Hospital Infection Control Committee.

Measures to control spread of antibiotic resistance:

I .Appropriate antimicrobial use:

1. Each health care facility should have an antimicrobial use programme. The goal is to ensure effective economical prescribing to minimize the selection of resistant microorganisms.

2. Formulation of guidelines with a multidisciplinary approach using the local antibiogram.

3. Provide ongoing education on rational use of antibiotics to clinicians and ensure implementation of antibiotic policies.

4. Restricted antibiotic use.

5. Use must be justifiable based on clinical diagnosis.

6. Before initiating antibiotic treatment, appropriate specimens for bacteriological examination must be submitted to laboratory and selection of an antibiotic must be based on the sensitivity pattern, patient tolerance, and cost.

7. An agent with as narrow a spectrum as possible should be used with appropriate dosage and duration of antimicrobial therapy.

8. The correct dose must be used.

9. Control antibiotic use - Selected antibiotics may be restricted in use. **Cyclic rotation** of antibiotics in a class - Discontinuation of antimicrobial therapy based on predefined criteria.

10. Carry out periodic prescription audits.

11. Restriction of hospital formulary through pharmacy.

12. Standard and contact Precautions including rigorous adherence to hand hygiene, appropriate use of PPE.

13. Isolation and cohorting of patients infected or colonized with Multi-drug resistant organisms (MDROs).

14. Education and training of Health Care Pharmacist (HCP).

15. Increased environmental cleaning and patient-dedicated equipment.

16. Proper sterilization and disinfection.

17. Surveillance for Multidrug resistant organisms (MDRO's) especially in high risk areas.

Screening of patients and staff for multi drug resistant organisms (MDROs)

INTRODUCTION

MDRO can be defined as a bacterial isolate which is resistant to one or more agents in three or more different classes of antimicrobials that the isolate is expected to be susceptible to.

Endemic MDROs	Emerging MDROs
• Methicillin-resistant *Staphylococcus aureus* (MRSA) • Multi-resistant Pseudornonas species • Multi-resistant Acinelobacter species • Vancomycin-resistant *Enterococcus (VRE)*	• Carbapenem resistant Enterobacteriaceae (CRE) • Vancomycin-resistant *Staphylococcus mimics (VRSA)*

Importance of MDROs in Hospitals:

The morbidity and mortality rates associated with MORO infections are high and the spread of MDROs in hospitals will increase the burden on healthcare infrastructure contributing to increased costs of care due to prolonged hospital stays and the need for more expensive drugs. Stringent infection control strategies should be developed to prevent

and control the spread of MDROs and to minimize the risk of cross infection to other patients, staff and visitors.

Factors aiding in the transmission and persistence of MDROs in hospitals:

- Presence of vulnerable patients (with compromised immunity and indwelling devices)
- The reservoir of infected or colonized patients
- The selective pressure exerted by antimicrobial use
- The effectiveness of local infection prevention and control measures

PREVENTION AND CONTROL STRATEGIES FOR MDROs

A two level approach has been recommended for the prevention and control for MDROs:

1. Core strategies Applicable in any situation where MDRO infection or colonization is suspected or identified

2. Organism-based or resistance mechanism -based approaches: Applicable if incidence or prevalence of MDROs are not decreasing despite implementation of the core strategies Core strategies

The implementation of transmission-based precautions for all patients colonized or infected with MDR0s, which include!

- Performing hand hygiene and putting on gloves and gowns before entering the patient-care area
- Using patient-dedicated or single-use non-critical patient-care equipment
- Using a single-patient room or cohorting patients with the same strain of MDRO in designated patient-care areas
- Ensuring consistent cleaning and disinfection of surfaces in close proximity to the patient.

Organism-specific approach

Recommended when the incidence or prevalence of MDROs is not decreasing despite implementation of the core strategies and this approach focuses on:

- The type of MDRO (e.g. prioritization of available isolation facilities)
- The healthcare area (e.g. intensive care or other units with higher risks of transmission)
- Patient factors (e.g, whether the consequences of infection are severe)

• Available resources (e.g. feasibility of screening)

• Whether interventions to interrupt transmission are available (e.g. decolonization for MRSA)

Further Measures

I. Targeted screening-Timely active screening to identify colonized patients combined with the use of contact precautions. Screening involves collecting specimens Iron] the patient with subsequent laboratory analysis of samples. In a risk assessment approach to screening, considerations include the endemicity, the prevalence of infection, and the likelihood of MDRO carriage. Clinicians and the infection control professionals should be informed of both negative and positive screening results promptly.

2. Decolonization- Interventions may be topical, systemic or combinations of systemic and topical therapy. Topical include use of chlorhexidine whole body washes and topically applied antimicrobial agents like mupirocin. Systemic includes orally administered antibiotics (tetracyclines, fusidic acid, ciprofloxacin, rifampin and trimethoprim-sulfamethoxazole)

3.Surveillance and timely feedback- Increased surveillance is important to monitor the effect of interventions designed to control particular MDR s. Surveillance information should be fed hack to health care workers and facility management promptly

Antibiotic Stewardship is a key strategy to decrease the incidence of MDROs in hospitals

MDRO clearance criteria for patients

1. More than 3 months elapsed time from the last positive specimen

2. All wounds healed, no indwelling medical devices present

3. No exposure to any antibiotic or antiseptic body wash for at least 2 weeks prior to screening

4. In the case of MRSA, no exposure to specific anti-MRSA antibiotic therapy in the past three months

5. Consecutive negative screens from screening sites on two separate occasions OR evaluation of a single set of screening swabs with a broth amplification technique

Some patients with VRE may appear to be 'clear' with time but relapses with antibiotic therapy. Admission and interval screening in specialized units is an important way to detect new or relapsed VRE or MDR-GNB colonization.

<u>METHICILLIN RESISTANT STAPHYLOCOCCUS AUREUS (MRSA)</u>

Active surveillance cultures help to identify colonized MRSA patients in a facility or in a specific unit and to evaluate the success of an intervention that was implemented in response to increased MRSA infections or a MRSA outbreak

Suggested approach to screening for MRSA

Whom to screen:

I .Patients at high risk of carriage (Group I): Known to be previously infected or colonized with MRSA, frequent re-admissions to hospital, those from known MRSA prevalent community

2. Healthcare workers (Group 2) epidemiologically linked to single-strain outbreak in hospital

3. Patients in high-risk units (Group 3): ICU/high dependency unit. burns & pre-operative unit

When to screen:

I. Group 1 and Group 3 - At the time of admission

2. Group 2- After confirmation of epidemiological evidence and 2 weeks after decolonization

Samples:

Swabs from nose, perineum /groin, operative and wound sites, abnormal or damaged skin.

Laboratory identification:

1. Direct culture methods: Mannitol salt agar with 6 µg/ml of Oxacillin/ Chromogenic media
2. Broth enrichrnent culture

3. PCR to detect Alec -A gene

Management:

Apply stringent hand hygiene, contact precautions and core strategies including isolating and cohorting patients. increased environmental cleaning and dedicated patient equipment Tagging of MRSA positive patients for easy identification on readmission

Decolonization therapy for MRSA

Recommended for

• Healthcare workers epidemiologically linked to transmission

• Patients having prolonged hospitalization

• Patients with chronic conditions likely to be readmitted

• Patients before undergoing high-risk elective surgery

Regimen recommended:

• 2% mupirocin ointment three times a day for 5 days -- Prolonged or repeated courses should be avoided to prevent emergence of mupirocin resistance.

• Chlorhexidine bath or Octenidine wash is also recommended as an alternate.

→ Low level (MIC 8-256mg/L)

Mupirocin resistant MRSA → Treatment success rate of 80%

High level (MIC > 512 mg/L)

Naseptin (0.5%neomycin and 0.1%

Chlorhexidine) four times a day for 10 days

If neomycin resistant – Prontoderm (polyhexamethylene buguanide)

MRSA Clinical Information Records include

- All MRSA positive microbiology result (screening, culture or PCR result etc.) within the last 2 years from the date of request, including the date of test, the specimen type and the laboratory that performed the test.
- All MRSA screening results (including positive and negative)within the last 2 years from the date of request , including the date of test and the laboratory that performed the test.

MRSA Tagging

Hospitals should tag all patients who are found to be MRSA positive.

MRSA Untagging

Hospitals can consider untagging patients with a past history of MRSA positivity, if the patient has either;

- Undergone decolonization with Chlorhexidine bath or Octenidine wash and Mupirocin nasal cream for at least 5 days is completed in any hospital and 3 negative screening culture from nasal, axillae and groin (NAG),with first sample at least i week after decolonization therapy.
  OR

- If no decolonization, the patient in the hospital must meet one of the following criteria. More than 2 years since the last positive culture 3 negative NAG screening cultures (at least 1 day apart)

<u>VANCOMYCIN RESISTANT ENTEROCOCCI (VRE)</u>

Active surveillance cultures should be undertaken on the following patient groups

1. Patients admitted to high risk areas (ICU, transplantation units)
2. Patients known to be VRE positive, upon re- admission to hospital
3. Patients transferred from other hospitals

4. “At risk “patients who have been contacts of known VRE positive patients.

Laboratory identification

- Rectal swab or faeces is the recommended specimen for surveillance
- Sodium azide agar with 6 μg/ml of Vancomycin or Chromogenic media can be used for detection of VRE from screening samples, PCR detection of resistant genes.

Management

- Apply stringent hand hygiene, contact precautions and core strategies including isolating and cohorting patients, increased environmental cleaning and dedicated patient equipment.
- Gastrointestinal colonization with VRE may persist for long periods of time and serves as a reservoir for transmission of VRE to other patients.

Hospitals should tag all patients who are VRE and can consider untagging if the patient has either; more than 2 years since the last positive culture OR 3 negative rectal screening cultures (at least 1 month apart)

•HCW screening and decolonization is not recommended for VRE.

CRE (CARBAPENEM RESISTANT ENTEROBACTERIACEAE)

Mechanisms of CRE:

I. The production of a broad-spectrum lactamase enzyme(carbapenemase)

2. Increased permeability of the bacterial cell wall for the antimicrobial due to porin loss.

Commonly encountered CRE’s are:

Klebsiella pneumoniae carbapenemase (KPC), New Delhi metallo- β-lactamase (NDM), Oxacillinase (OXA), Verona Integron-encoded metallo-β-lactamase (VIM) and Imipenemase Metallo-beta-lactamase (IMP).

Risk Tailors for acquisition of CRE:

•Exposure to broad-spectrum antimicrobials, such as cephalosporins, β lactam-β lactarnase inhibitor combinations, Fluoroquinolones.

• Prolonged or recurrent hospitalization

• ICU admission

• Presence of central vascular catheters

• Long term urinary catheterization

The gastrointestinal tract is the common site for asymptomatic colonization with CRE in patients and contaminated hands of healthcare workers have been implicated in hospital outbreaks of CRE.

Laboratory identification:

• Active surveillance cultures for rectal carriage is recommended for high- risk patient groups, but not recommended for IICW screening

• Rectal swab or faeces is the recommended specimen for surveillance. Specimens taken from other sites(urine. swabs from skin breaks or manipulated sites) can also be used.

• Chromogcuic media for detection of CRE from stool samples or other rapid tests like CarbaNP which directly detect carbapenem hydrolysis. PCR for confirmation

When CRE isolate is detected from a clinical specimen on a ward or unit. Surveillance screening by a rectal swab is recommended for patients with epidemiological link to the index case.

Patients should be informed of their positive status for colonization or infection.

Treatment:

Decolonization of asymptomatic colonizers of CRE is not recommended as the effectiveness of treatment is not proven.

References:

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Antimicrobial Stewardship:

This aims to optimize antimicrobial use among patients in order to reduce antibiotic resistance, improve patient outcomes and safety, and ensure cost-effective therapy.

At the healthcare facility level, antibiotic stewardship involves:

• Implementing an antibiotic stewardship program; and

• Continuous monitoring and analysis of antibiotic usage, to track changes in antibiotic resistance and to monitor effects of containment strategies.

Key requirements of a healthcare facility antibiotic stewardship program:

1. A multidisciplinary antibiotic stewardship team with core membership of an infectious diseases physician (lead doctor) and a clinical pharmacist. Microbiologist, and infection control professional may also be included.

2. Antibiotic stewardship should be available within the healthcare facilities for quality improvement and patient safety governance structure. There should be collaboration between the stewardship team and drug and therapeutics and infection prevention and control committees.

3. Implementation of clinical guidelines that comply with national treatment guidelines and incorporate changes regularly based on resistance patterns prevailing in the health facility as reported regularly by microbiology department.

4. Microbiology services reporting patient-specific culture and sensitivity results to optimize individual antibiotic management.

5. Review of antibiotic prescribing with intervention and direct feedback to the prescriber.

6. Activities according to local priorities and resources & provision of effective & regular education of prescribers and pharmacists about antibiotic usage, development of resistance and judicious prescribing of the antibiotics.

7. Point of care interventions including: streamlining or de-escalation of therapy, dose optimization, parenteral to oral conversion.

8. Use of information technology such as electronic prescribing with clinical decision support, on-line approval systems.

9. Monitor antibiotic prescribing by measuring antibiotic consumption; drug use evaluations and using quality & use of Medicine indicators.

10. Support and collaboration of hospital administration including allocation of resources to provide education and measure and monitor antibiotic usage.

11. Antibiotic stewardship surveillance methods should be established at patient level as well as population or community level.

Principles for use of antibiotics

1. Before starting any empiric antibiotic treatment, minimum two sets of blood cultures should be taken from different sites.

2. Prior to initiation of antibiotic therapy, appropriate specimens should be sent for gram stain and culture. Antibiotic choice must be adjusted according to culture results once they are available.

3. Antibiotic doses recommended in the various guidelines are for patients with normal renal and hepatic function only. Dose adjustments should be made for patients with renal and hepatic function.

4. Convert patients to oral antibiotics once they fulfill the IV-to-PO switch protocol criteria stated in Fig. 3.

5. Antibiotics marked with asterisk (*) are restricted to ID, Respiratory & ENT physicians only. For physicians from all other departments, please call ID physician on-call to approve the empiric use of these restricted antibiotics.

Advantages of oral therapy:

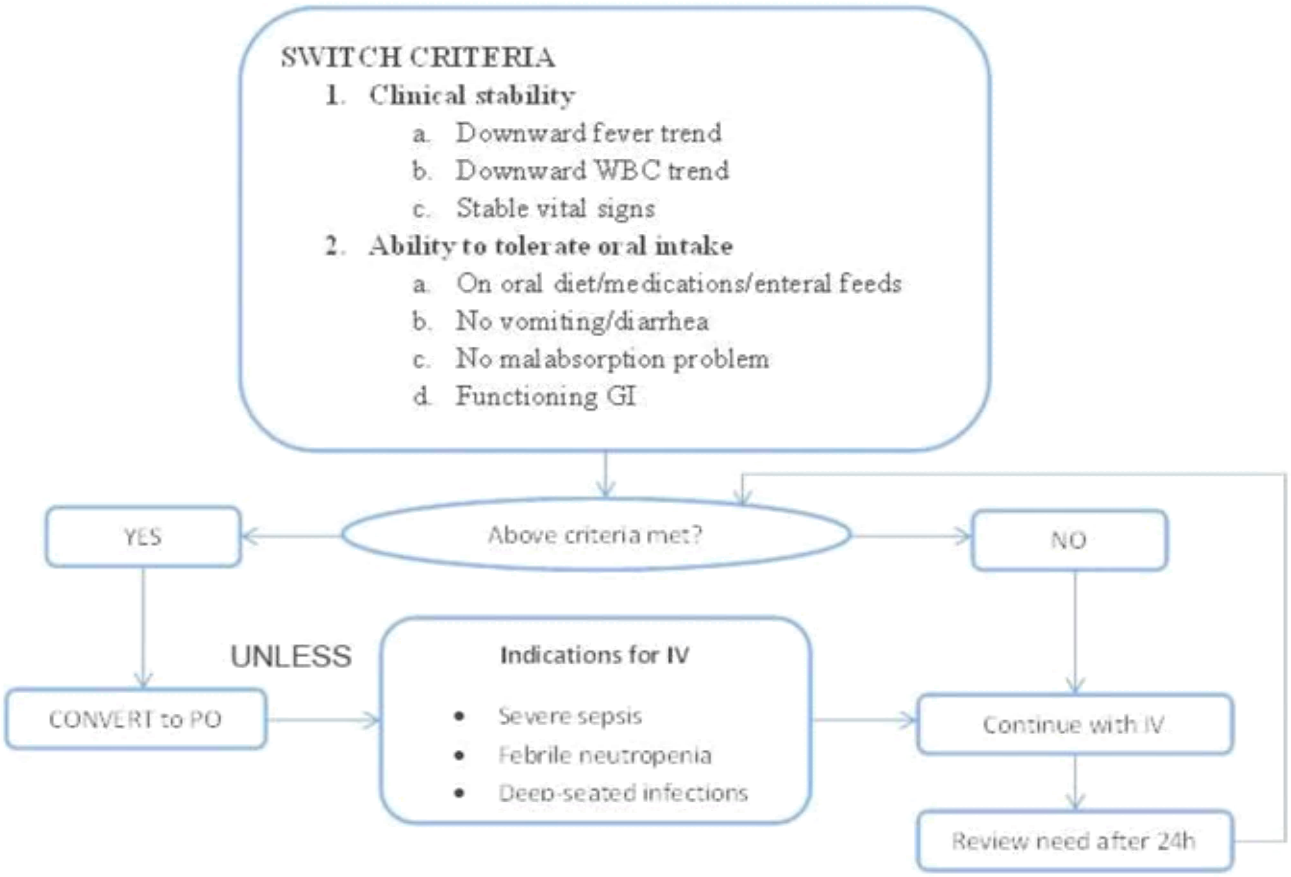
- ϖ Drug cost savings
- ϖ Ease of administration
- ϖ Early discharge opportunity

- Decreased IV-related adverse events

Antibiotics suitable for IV-to-PO conversion (Bioavailability ≥90%):

- Ciprofloxacin (~80%)
- Levofloxacin
- Moxifloxacin
- Clindamycin
- Metronidazole
- Co-trimoxazole
- Fluconazole

Fig: Intravenous-to-oral antimicrobials conversion



Courtesy: Hospital infection control guidelines-ICMR-2016

Empiric use of carbapenems (Ertapenem should not be used for empiric therapy)

1.Appropriate criteria A (patients in ICU or HD) *(must qualify all)*

a. Sepsis

AND

b. Clinically unwell (drowsy/confused, saturation oxygen <92%, systolic blood pressure <90% OR

Respiratory rate >30 breaths/minute)

AND

c. Onset of infection either nosocomial (>48 hours after admission) OR health care-associated

Sepsis is the systemic response to infection. In sepsis, the clinical signs describing systemic inflammatory response syndrome (SIRS) are present together with definitive evidence of infection. SIRS is defined as 2 or more of the following variables:

- ϖ Fever of more than 38 ºC or less than 36 ºC
- ϖ Heart rate of more than 90 beats per minute
- ϖ Respiratory rate of more than 20 breaths per minute or a PaCO2 level of less than 32 mm Hg
- ϖ Abnormal white blood cell count (>12,000/µl or <4,000/µl or > 10% bands)

2.Appropriate criteria B (general ward) (must qualify all)

a. Patients with severe nosocomial and health care-associated infections who failed to improve after 48-72 hours of empiric therapy

AND

b. Appropriate cultures remain negative

Health care-associated infection can be defined as infection in a patient with at least one of the following risk factors:

- ♣ Hospitalization in an acute care hospital for two or more days in the last 90 days;
- ♣ Residence in a nursing home or long-term care facility in the last 90 days
- ♣ Receiving outpatient intravenous therapy (like antibiotics or chemotherapy) within the past 30 days Attending dialysis center in the last 30 days

3.Appropriate criteria C

Patients with:

a. Febrile neutropenia

b. Severe necrotizing pancreatitis

c. Suspected severe melioidosis

4.Appropriate criteria D

Empiric therapy for nosocomial organ infection when delay in appropriate therapy could pose catastrophic risk (e.g. mediastinitis, brain abscess etc)

Carbapenem definitive (culture directed) use guideline

1. Ertapenem should be used only for infections caused by ertapenem susceptible Gram negative bacteria that are resistant to other beta-lactam antibiotics or/and quinolones.

2. Meropenem/Imipenem is preferred agent for *Pseudomonas aeruginosa, Acinetobacter baumannii* and other Gram negative bacteria that are resistant to other beta-lactam antibiotics (including ertapenem).

3. Carbapenems can be used to treat other infections caused by Gram-negative bacteria in patients with non-severe allergy and/or intolerance to active penicillins and/or cephalosporins when isolate is resistant to other classes of antibiotics (e.g. Quinolones).

Antibiotic challenge should be conducted ONLY after consultation with allergy specialist. (Severe penicillin allergy is defined as bronchospasm, hypotension, angioedema, urticarial, bullous eruption and Stevens - Johnson syndrome.)

4. It is recommended that carbapenem antibiotics be endorsed by an ID physician within 48 hours of commencement and re-evaluated every 48 hours.

For high end antibiotics such as Colistin, Tigecycline, fosfomycin, daptomycin, etc., they may be endorsed by an ID physician/physician within 24 hours of commencement and re-evaluated every 48 hours.

Considerations for use of antibiotics in pregnancy and pediatrics

- ϖ In pregnancy it is recommended to avoid tetracyclines, quinolones and high dose Metronidazole (2g).
- ϖ Short-term use of trimethoprim (unless low folate status or taking another folate antagonist such as antiepileptic or proguanil) or nitrofurantoin (at term, theoretical risk of neonatal haemolysis) is unlikely to cause problems to the fetus.
- ϖ Antimicrobial agents in pregnancy and lactation are limited, and antimicrobial agents should be prescribed with caution.

C. Guideline for Antibiotic Treatment and Prophylaxis:

Common Pathogen	1st Line	2nd Line	Comment
Acute viral infection	No Antibiotic	Antiviral	Symptomatic
Viral with secondary infection	-Betalactam agents -Macrolides	3rd Generation cephalosporins	-
Acute Bacterial infection	- 2nd gen cephalosporin & 3rd generation cephalosporins 1st gen Fluoroquinolones Aminoglycosides	Beta-lactams+Beta-lactamase inhibitors Carbapenems Vancomycin	-
Mix Bacteria infection Gram+ve, Gram-ve	Broad spectrum antibiotic of any generation Aminoglycosides	As per culture sensitivity result	-
Mix Anaerobic infection	Broad-spectrum antibiotic Carbapenems Metronidazole Cefoxitin Beta-lactams+Beta-lactamase inhibitors	As per culture sensitivity result	-
Worm infestation	Antihelminthics Specific or Broad specific		-
Fungal	Ketaconazole, , Miconazole,Fluconazole	With suitable Antibiotics	-

Tuberculosis	As policy of DOT's clinic		-
Amoebic infection	Anti amoebics		-
Malarial Parasite	Chloroquines and Primaquines	Artesunate Artemether	Resistant cases Quinine Derivatives

Note: As per 2017 WHO guidelines Antimicrobials under RESERVE group are: 1. Aztreonam 2.Cefepime 3.Ceftaroline 4.Polymixin 5. Linezolid 6.Tigecycline 7. Daptomycin

SVIMS hospital implements the antibiotic policy and monitors rational use of antimicrobial agents*

SVIMS hospital has released Antimicrobial Stewardship Pocket guide and it is revised every six months & uploaded in the SVIMS website.

ANTIMICROBIAL STEWARDSHIP (AMS PROGRAMME)

- **Objectives:** To provide the importance of antimicrobial stewardship programme and challenges while implementing the programme in the hospital and their solutions.
- It provides the necessary recommendations to the healthcare workers in hospitals to improve the quality of antibiotic prescribing and thereby improve patient clinical outcomes.

WHY TO IMPLEMENT ANTIMICROBIAL STEWARDSHIP IN HOSPITALS?

Antimicrobial resistance (AMR) is a rising threat cross the global. There is a dramatic increase in the antimicrobial resistance in the recent days and many of those are multidrug resistance (MDR). The multidrug resistance organisms (MDROs) are prevalent in each and every country though the extent and the severity of the problem vary.

Misuse and over-use of antibiotics

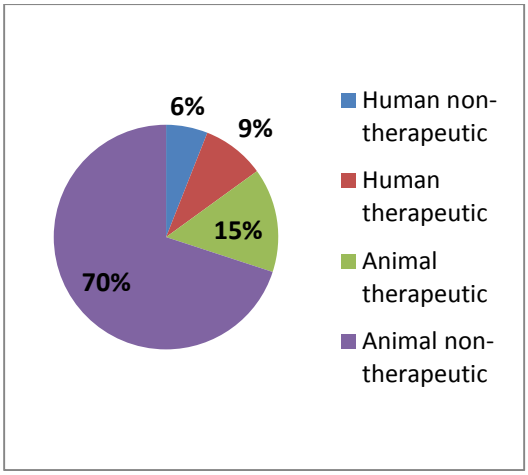
Since the discovery of penicillin, there have been widespread use of antibiotics In hospital and community settings, Though last seven decades witnessed that the antibiotics were highly effective and have saved millions of lives, at the same time, this has also led to their misuse

through various ways such as use without a prescription and overuse for self-limiting infections, non-bacterial infections and treatment of colonization.

Antibiotics are used in various sectors, Interesting fact is world's largest antibiotic use occurs for animal no-therapeutic purpose(70%), followed by animal therapeutic purpose)15%), Human use accounts for only 15% of total antibiotic consumption out of which only 9% are used for human therapeutic purpose. This date explains that just brining is stewardship programme in health care facility won't bring down antibiotic use dramatically, A robust plan should also be in place for control of antibiotic use in animals.

Poor antibiotic research and development

Unfortunately there are not many researches going on for the development of newer antibiotics especially when it comes to antibiotics active against Gram-negative bacteria. Research and development of any antibiotic is a huge investment for the pharmaceutical industry. More so, soon after the discovery of the antibiotic, the bacteria develop resistance mechanisms to tackle the antibiotic. As a result the investment goes waste, Lack of profitability has forced pharmaceutical industry to graze in fresh meadows, leaving the field of anti-infective research quite barren, That is also hypothesized that there could be a return to the pre-antibiotic era, where many people could suffer or die from untreatable bacterial infections.



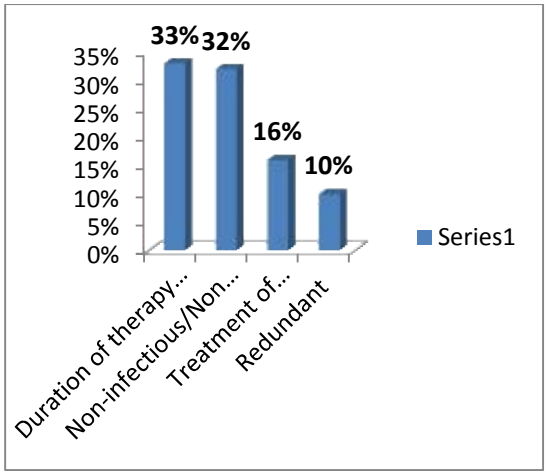


Fig-1 Current use of antibiotics in the world

Fig-2: Unnecessary Antimicrobial therapy

Antimicrobial prescribing Facts: The 30% rule

Hoffman et al in 2007 have described that Antimicrobial prescribing facts follow 30% rule. Although there is no clear cut data available for India, but it is believed that the situation is same or even worse in Indian scenario.

- Nearly 30% of all hospitalized inpatients at any given time receive antibiotics
- Over 30% of antibiotics are prescribed inappropriately in the community
- Up to 30% of all surgical prophylaxis is inappropriate
- About 30% of hospital pharmacy costs are due to antimicrobial use
- 10 – 30% of pharmacy costs can be saved by antimicrobial stewardship programs

ANTIMICROBIAL STEWARDSHIP

Antimicrobial stewardship (AMS) is one of the key strategies to overcome antimicrobial resistance. It involves the careful, judicious and responsible management of antimicrobial use.

Definition

There are many ways of Antimicrobial stewardship can be defined.

"Antimicrobial stewardship" is an inter-professional effort, across the continuum of care involves timely and optimal selection, dose and duration of an antimicrobial for the best clinical outcome for the treatment of prevention of infection with minimal toxicity to the patient and minimal impact on resistance and other ecological adverse events such as *Clostridium.difficile'* [Nathwani et al., 2102] CDC has defined **"Antimicrobial stewardship"** as-

- The right antibiotic
- for the right patient,
- At the right time.
- with the right dose, and
- the right route, causing
- the least harm to the patient and future patients (www/cdc.gov/getsmart/healthcare/inpatient-stewardship)

1. Goals of Antimicrobial stewardship

- Restricting antibiotics results in reduction of antibiotic pressure which in turn prevents the development of antimicrobial resistance.
- Restricting antibiotics can reduce colonization or infection with Gram-positive or Gram –negative resistance bacteria.

2. Goal 2: Improve patient outcomes

* Improve infection cure rates

* Reduce surgical infection rates

* Reduce mortality and morbidity

3. Goal 3: Improve patient safety

- Reduce antimicrobial consumption, without increasing mortality or infection-related readmissions e.g.22% - 36% reduction in antimicrobial use [Dellit et al ., 2007]
- Reduce C.difficile colonization or infection by controlling the use of "high –risk "antibiotics [Valiquette et al., 2007]

4. Goal 4: Reduce healthcare costs towards antimicrobial expenditure without adversely impacting quality of care

IMPLEMENTATION OF ANTIMICROBIAL STEWARDSHIP PROGRAM

The six steps of Antimicrobial stewardship programme (AMSP) are depicted in table-1.

Table-1-Key steps for implementing an Antimicrobial stewardship programme (AMSP)

1. Administrative support (Leadership)
2. Assess the situation
   - Supporting infrastructure
   - Supporting manpower
3. Set up AMS team
4. Frame Antimicrobial policy-Hand book with system wise indications
5. Implement AMS strategies
   - Front end strategies – Formulary restrictions
   - Back end strategies – Antimicrobial review methods (prospective audits and pharmacy driven AMSP)
6. Educate and train

Step-1: Administrative support (Leadership)

The most important prerequisite for implementing AMSP is a strong administrative support. None of the efforts of ID physicians, Microbiologists, or infection control specialist to establish AMSP are likely to be successful without active involvement by hospital leadership. The role of administrators' are-

- Publicly committed to the program –Hospital administrators should play a front role and show leadership quality while implementing AMSP. Many a times, it is observed that AMSP is initiated by ID physicians or microbiologists, or infection control specialists and they try to convince the administrators to provide a passive support. All those attempts often fail because stakeholders of the program will be adhering to the policy guideline.

- Program funding – Without adequate support form hospital leadership, program funding will be inadequate or inconsistent since the programs do not generate revenue although they may result in significant cost savings.

7. Freedom and power to AMS team – Hospital administrators should provide the liberty, freedom and power to the members of antimicrobial stewardship team to execute the policy.

Step – 2: Assess the situation

The hospital administrators should analyse the situation and what problems they want to address. There are many international guidelines available but those need to be adapted them to the local situation. Define where you are and where you want to go, with quantitative figures. The followings should be assessed first before implementing AMSP.

2 A) Assess the diagnostic support available-

Availability of a rapid microbiology diagnostic tools and biomarkers is recognized as a key intervention in implementation of antimicrobial stewardship in hospitals. The diagnostic facility should be improved first before start implementing AMSP in the hospitals. However, the availability of these facilities in resource-limited hospitals is likely to be a challenge to their introduction. But the administrators should realize that additional budget needed for these investigations will be much lesser compared to the cost saving which can be achieved by rationalizing the use of antibiotics.

A. Complete automation of microbiology – This is an essential requirement before implementing will achieve better clinical outcomes and timely streamlining /de-escalating of empiric broad – spectrum antibiotics in seriously ill patients. The various diagnostic facility available are –
    - Culture automation-BACTEC or BacT/Alert
    - Identification automation – A MALDI-TOF
    - Antibiotic susceptibility testing automation – by Phoenic or Vitek (it gives results in MIC which is more reliable and accurate then disk diffusion method)
B. Rapid Identification systems Such as near-patient rapid tests can be revolutionized. For example, bed side rapid tests for influenza and Strep A can be useful to identify patients with bacterial versus viral infections.
C. Rapid molecular diagnostic screening tests play an important role in pathogen detection in critically ill patients which will improve antibiotic stewardship and clinical outcomes.

Film array (biomerieux system – It is an FDA, CE-IVD, and TGA certified multiplex PCR system that integrates sample preparation, amplification, detection and analysis. This simple system requires just 2 minutes of hands-on time, with a total run time of about an hour.

1. Respiratory panel : tests for a comprehensive panel of 20 respiratory viruses and bacteria

2. Blood Culture identification panel: tests for a comprehensive list of 24 pathogens and 3 antibiotic resistance genes associated with bloodstream infections.
3. Gastrointestinal Panel: tests for 22 common gastrointestinal pathogens including viruses, bacteria and protozoa that cause infectious diarrhea.
4. Meningitis Encephalitis Panel : tests directly in CSF for the 14 most relevant ME –associated pathogens including bacteria, viruses and a parasite

D. Biomarkers for sepsis e.g. Procalcitonin – Procalcitonin (PCT) has been used as a rapid testing biomarker of bacterial infection, a very important interventional tool for antibiotic stewardship. There are several biomarkers that are used to guide initiation, and stop of antimicrobial therapy.

Biomarkers	Role in AMSP
IL-6	Show a fast initial spike upon infection with, however, levels going back to normal within a few hours. The high variability of these markers has been a major challenge for their use in clinical practice.
C-Reactive protein (CRP)	Increases slowly with a peak after 48 – 72 hours and show decrease thereafter. CRP is usually considered a biomarker for inflammation rather than infection.
Procalcitonin (PCT)	It is detectable within 2 – 4 and peaks within 6 – 24 hours and decreases daily by around 50% if the bacterial infection is controlled by the immune system supported by effective antibiotic therapy. These characteristics make PCT an interesting biomarker for monitoring patients with systemic infections and sepsis and for more informed decisions on prescription and duration of antibiotic therapy. As PCT levels do not show a steep decrease in non-responding infections, monitoring its course also has prognostic implications.

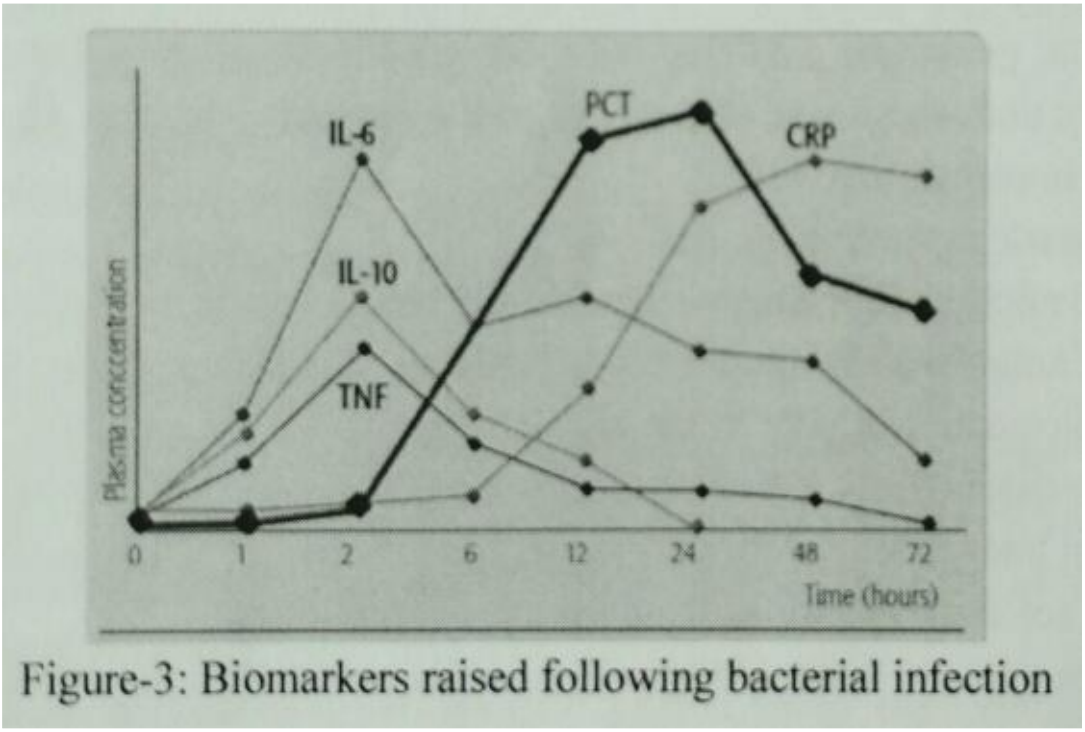


Figure -3: Biomarkers raised following bacterial infection

Procalcitonin

Procalcitonin is a prohormone of the calcium homeostasis hormone calcitonin.

- Normally, it is produced I the Neuro-endocrine medullary C –cells of the thyroid gland at a very low concentrations (<0.05 ng/ml)
- Bacterial infections selectively induce an increase in the concentration of PCT (in multiple parenchymal tissues) because both endotoxins (lipopolysaccharide) form the bacterial cell wall and host responses to infection stimulate the production of PCT by cytokines, such as IL-1β,IL-6 TNFα.
- The up-regulation of PCT correlates with the severity and extent of bacterial infections.
- This results in an accumulation of PCT because, unlike neuroendocrine cells, parenchymal cells lack the ability to cleave procalcitonin into its mature form, calcitonin.
- Conversely, Interferon-γ,a cytokine released in response to viral infections (marker of CMI), blocks the up regulation of PCT, resulting in a higher specificity of PCT toward bacterial infections.
  Thus, PCT helps to distinguish severe bacterial infections from milder viral illnesses.

- PCT production is not impaired by neutropenia or other immunosuppressive states.
- PCT levels parallel the severity of the inflammatory insult or infections meaning those with more severe disease have higher levels.

- Furthermore, procalcitonin has some utility as a prognostic indicator with higher serum concentrations related to the risk of mortality.
- Advantage over CRP and WBC count : These advantages include specificity for bacterial infection, the rapidity of its rise after an insult (6h), the rapid decline with immune control on infection (half life of 24 h), excellent correlation with severity of illness (higher levels in more severely ill), and the lack of impact to anti-inflammatory and immunosuppressive states on production.
  PCT is used as a guide in the following situations:

  1. Differentiation of bacterial verses viral respiratory tract infection.
  2. Determination of the duration of antibiotic treatment in respiratory infections.
  3. Diagnosis and monitoring of sepsis and septic shock.
  4. Prognostic usefulness in classifying the patients as low risk or high risk for bacterial infection and /or sepsis and prediction of mortality.
  5. Monitoring the response to antibacterial therapy.
  6. Differentiating bacterial verses viral meningitis.
  7. Diagnosis of bacterial infection in neutropenic patients.

Importance of Interpreting Susceptibility Reports (disk diffusion and MIC) for AMSP

Determination of the antimicrobial susceptibilities of significant bacterial isolates is one of the principal functions of the clinical microbiology laboratory. From the physician's pragmatic point of view, the results of susceptibility tests are often considered important or more important than the identification of the pathogen involved. This is particularly true in an era of increasing antimicrobial resistance, in which treatment options are at times limited to newer, more costly antibacterial agents.

High priority has to be given not only to producing technically accurate data but also to reporting those data to physicians in an easily interpretable manner. Result is generally reported as category:

"Susceptible" – Implies that there is a high probability that the patient will respond to treatment with the appropriate dosage regimen for that antimicrobial agent.

"**Intermediate"** (buffer zone) – With agents that can be safely administered at higher doses or that the agent may prove efficacious if it is normally concentrated in an infected body fluid, e.g., urine Conversely, for body compartments where drug penetration is restricted even in the presence of inflammation (e.g., cerebrospinal fluid),it suggests that extreme caution should be taken in the use of the agent.

"Resistant" – Implies that treatment with the antimicrobial agent is likely to fail.

"Susceptible-dose dependent" – New category for antibacterial susceptible testing. Category implies that susceptibility of an isolate is dependent on the dosing regimen that is used in the patient SDD has been included within the intermediate category definition for antimicrobial agents. SDD is more specific and it conveys clinicians that a higher dose can be considered for isolates with MICs (or zones) that in this interpretive category.

Organisms tests as "susceptible" to that treatment, and success my still occur in around 60% of cases when the organism test as "resistant" to the agent used. The apparent 60% response rate to ineffective antimicrobials is said to reflect the natural response to many bacterial infections in an immunologically normal host.

Antibiotic Titrations: The intrinsic activity of antimicrobial drugs in vitro is usually expressed in terms of the minimum inhibitory concentration (MIC). These values are derived by titration of the drug against a standard inoculums of a pure culture if an isolated bacterial species in broth or on agar plates. The MIC is the lowest concentration that prevents the development of visible growth after a period of incubation that is usually 16 – 20 hours for most common pathogens.

MIC is the mainstay of modern pharmacodynamics principles on the best antibiotic dosing schedules and is certainly the single most important measure of an antibiotic's activity.

Process of setting Epidemiological Cut-offs and Breakpoints

EUCAST takes a different approach to developing interpretive criteria for MICs and disk diffusion results than does the CLSI. EUCAST first establishes epidemiological agent (78). Once the wild-type population has been described and epidemiological cut-offs been decided, the wild-type distributions are categorized as susceptible, intermediate or resistant, using pharmacokinetic/ pharmacodynamics data and clinical data. The clinical breakpoints guide therapy, while the epidemiological cut-off values are valuable for sensitive and early detection of emerging resistance.

According to European Committee on Antimicrobial Susceptibility Testing recommendation Carbapenems are compared according to the susceptible, intermediate or resistant categories. This new approach allows comparing these carbapenems in a `MIC score' talking into account the differences in breakpoints between drugs. MIC also helps to identify the profile of new drugs so that their clinical value is determined.

Clinical situations where MIC determination is essential clinically:

- Endocarditis
- Meningitis

- Endopthalmitis
- Sepsis
- Osteomyelitis
- Immunosuppressed patients
- Prosthetic devices
- Patient no responding despite `S'

In addition to clinical indications MIC is essential for

- Colistin for Enterobacteriacae and Acinetobacter spp
- Vancomycin and daptomycin for S.aureus
- Levofloxacin for B.cepacia
- Oxacillin disc < 20 mm for S.pneumoniae
- Penicillin/Ampicillin for VGS in sterile sites
- Ticarcillin/Clavulanic acid, Chloramphenicol, Ceftazidime for S.maltophila

2 B) Assess the pharmacodynamics support available-

E. Monitoring of serum antibiotic level by HPLC (high performance liquid chromatography)
F. Monitoring antibiotic quality by HPLC (high performance liquid chromatography)

2 C) Assess the manpower support available:

- ID physician (dedicated)
- Fully functional HICC and designated infection control officer
- Stewardship nurses
- Clinical pharmacists
- 24/7 reporting facility for culture and sensitivity by Dept. of Microbiology

2D) Assess the information technology support available-

- Hospital information system (HIS)- Fully functional HIS including Laboratory information system will augment the stewardship program by many folds
- Computerized order-Entry and Decision support Systems

Step – 3 Set up AMS Team

Antimicrobial Stewardship team (AMS team) is a multidisciplinary committee who will be involved in executing the interventions (both front and back end strategy as described later) and evaluating the adherence to AMSP. The members of AMS team are –

- ID physician

- Stewardship nurses
- HICC – Infection Control Officer and nurses
- Clinical microbiologist
- Clinical pharmacist with expertise in infection
- Quality improvement/patient safety managers
- Pharmacy department

Leadership (Antibiotic steward)

An antibiotic steward is physician who is trained in infectious diseases and infection control or a microbiologist with training in infection control and antibiotic stewardship. In hospitals without an ID Physician or microbiologist, any clinican with special interest in infection control and antibiotic stewardship can function as an antibiotic steward.

- Antibiotic steward should be responsible for reviewing the antimicrobial prescriptions and giving a second opinion especially on the higher-end antibiotic usage.
- Availability of more than one antibiotic steward in any one hospital will proved flexibility in providing round the clock support.

Step -4: Frame Antimicrobial policy

Every hospital should frame their own hospital antibiotic policy in the form of a 'Handbook of Antimicrobial Use'. The core chapters of the Hand book have been depicted in table-2.

Treatment regimens of common infections of major systems-

This is the main component of the hand book; the major departments involved in each system should frame the antibiotic treatment regiments for 6the infectious diseases under that system

i) Reference to be flowed – Every antibiotic treatment regimen should be supported by a reference which has to be quoted in the chapters against each indication of antimicrobial use.
Some of the examples are given below.

   a. Harrision,IDSA (Infectious disease Society of America) – For Medicine
   b. Sabistob's textbook of Surgery
   c. Any other guideline/standard book for other dept
   d. Local Antibiogram should also be taken into consideration .However; guideline should not be made only based on local antibiogram pattern.

ii) Common consensus – after preparing the treatment regimen, the major departments involved for each system should initiate discussion among them to arrive at a common consensus.
   a. Intra Unit discussion

b. Intra departmental discussion
c. Inter Departmental discussion

iii) The AMS team members should coordinate via mail, personal and subgroup meetings with various departments to arrive at the common consensus.

iv) Every stakeholder's opinion and consensus should be taken so that once the Hand Book is implemented, maximum adherence can be obtained.

Figure – 4: Template for treatment regimens of common infections

c. Inter Departmental discussion

iii. The AMS team members should coordinate via mail, personal and subgroup meeting with various departments to arrive at the common consensus.

Iv. Every stakeholder's opinion and consensus should be taken so that once the Hand book is implemented, maximum adherence can be obtained.

Table-3: Chapter distribution of Handbook of Antimicrobial Use of a hospital

Chapters	Name of the Chapter	Should contains
1.	Title page	Name of policy, date, version, review date, and contact details for normal hours and out -of-hours enquiries
2.	Goal of AMSP	
3.	List of available antimicrobials	Unrestricted, restricted (approval of a specialist is required) or permitted ofr specific conditions
4.	General Guidelines	
5.	AMR Surveillance data of last year	Resistant pattern of common pathogens Overall, ICU/Ward/OPD wise, specimen wise
6.	**Treatment regimens of common infections** Should contain five columns- Disease, agents, antibiotic regimen in adult and children, comments/suggestions (See the template below in figure – 4)	
	Infection of major systems	**Major department Involved are -**
	I GI and Intra – abdominal Infections	Common/Surgery/Medicine/Medical and surgical Gastroenterology
	Ii CVS Infections	Medicine/Cardio/CTVS
	Iii Skin and soft tissue Infections	Common/Medicine/Surgery/Dermatology
	iv Bone and Joint Infections	Common/Ortho
	v Respiratory Infections	Common/Medicine/TB chest
	vi Genitourinary Infections	Common/Medicine/Urology/Nephrology/OBG/Dermatology (for STI)
	Vii CNS Infections	Medicine /Neuromedicine/Neuro surgery
	Viii Ocular Infections	Ophthamalogy
	Ix Dental Infections	Dental department

	X	Empiric antibiotic therapy for ICU	ALL ICUs
	Xi	Patients with fever Neutropenia	Oncology,Medicine
	Xii	Fir management in NICU	Neonatology,Pediatric surgery
	Xiii	Children column in each system	Pediatrics
	Xiv	Surgical site infections	Surgery and all surgical departments.
8		Frequently asked questions (FAQs)	

Figure – 4: Template for treatment regimens of common infections

GI and intra- abdominal indections				
Disease	Etiological agents	Antibiotics in adults	Antibiotics in children	Remarks/Alternative antibiotics
Acute Gastroenteritis	Viral Entero toxigenic and Enteropathogenic E.coli Non-typhoidal salmonella	No antibiotics usually required. prompt rehydrativion essential . if diarrhea persists beyond 2 daysor in immuno suppressed patients – ciprofloxacin 500 mgbd*5 days	Nil	When blood jor mucus appears in stool, or if there is evidence of cholera or invasive diarrhea; antibiotics are indicated in children
Cholera	V.cholerae	Cap. Doxycycline 300 mg. Single dose (6 mg/kg. maximum 300 mg or Tab. Ciprofloxacin 1 gm single dose	Ciprofloxacin single dose 30 mg/kg maximum1 g Above 8 years, Doxycycline 5 mg/kg to be preferred	Prompt rehydration essential ,antibiotic therapy is only adjunct to rehydration
Bacillary Dysentery	Shigella	Tab .Cefixime 400 mg od*5 days (8mg/kg/day) or Tab Ciprofloxacin 500 mg bd* 5 days	Tab. Cefixime (10 mg/kg/day/)*7 days. Continue feeding and add zinc supplementation	If no response then switch to cefoperazone sulbactum i.v (150 mg/kg/day)
Amoebic dysentery	Entamaoeba histolytica	Metronidazole 400 mg tds for 10 days	Metronidazole 30- 35 mg/kg/day in three divided doses for 10	

			days	

- Source : Antimicrobial Stewardship pocket guide, SVIMS

Step-5: Implement AMS strategies

Frontend strategies:

I) Formulary Restrictions:

This involves determining the list of restricted antimicrobial agents and criteria for their use combined with an approval system which is subject to regular audit and feedback to the prescribers. Though sounds more attractive and appears to be the most ideal way to achieve antimicrobial stewardship, but practically implementing formulary restrictions is not that easy. It creates lot of confusion as it directly impacts the clinician's freedom to choose antimicrobials. More so availability of the concerned authority to give approval all the time further complicates the problem especially in emergency situations. Hence, instead of surveillance on the usage of all antibiotics, monitoring higher-end antibiotics is a more practical and implementable strategy.

- Antimicrobials can be classified into restricted, semi-restricted and un-restricted groups (table-4).
- All antimicrobial prescriptions must be countersigned in duplicates by the consultants or faculty in charge of the unit, not by post graduate students or residents.
- Pharmacy will keep one prescription for its record purpose and will hand over the second prescription to the AMS team.

- The AMS team will review the antibiotic prescription and give a second opinion by countersigning on it. Further continuation of the antimicrobial use will depend upon the approval from AMS team. The duration to obtain the approval from AMS team can vary depending upon the class of antimicrobials.

  - Restricted antimicrobials: This group include third line antibiotics active against gram-negative bacteria such as Colistin, carbapenems and Tigecycline where more vigilant monitoring is needed. For these antimicrobials, pharmacy supply of >1 day can be made mandatory to obtain prior approval by AMS team.

  - Semi-restricted antimicrobials: This group include third and fourth generation cephalosporins and second line antibiotics active against gram-positive bacteria such as teicoplanin, vancomycin, daptomycin, Linezolid. For these antimicrobials, pharmacy supply of >3 days can be made mandatory to obtain prior approval by AMS team.
  - Unrestricted antimicrobial: This group include first & second generation cephalosporins, Cotrimaxazole, Azithromycin, clarithromycin and Fluoroquinolones where ales vigilant monitoring is needed. Pharmacy supply need not requires AMS team approval. However, retrospective review of antimicrobial use will be done by AMS team from time to time.

Table – 4 : Proposed formulary restriction

Restricted antimicrobial	Semi- Restricted antimicrobials	Unrestricted antimicrobials
Colistin Carbapenem Tigecycline	Teicoplanin Vancomycin Daptomycin Linezolid Third and fourth generation cephalosporins	First & second generation cephalosporins Co-trimoxazole Azithromycin Clarithromycin Fluoroquinolones
Pharmacy supply of >1days requires prior approval by AMS team (for second opinion) Pharmacy supply in duplicate prior to dispensing. Pharmacy will send the prescription for compulsory second opinion from AMS team within 24 hours	Pharmacy supply of >3days requires prior approval by AMS team (for second opinion) Pharmacy supply need a prescription in duplicate prior to dispensing. Pharmacy will send the prescription for compulsory second opinion from AMS team within 72 hours	Pharmacy supply does not requires AMS team approval. However, retrospective review of antimicrobial use will be done by AMS team form time to time.

2) Antibiotic cycling:

Antibiotic cycling or antibiotic rotation refers to the development of strategies utilizing the scheduled rotation of antimicrobials in order to minimize the emergence of bacterial resistance. Theoretically, during the periods when an antimicrobial is out of rotation (i.e. off the cycle) and its use is minimal, there won't be antibiotic pressure; as a result resistance to that drug will decline. These programs typically target gram-negative resistance and are generally limited to the ICU setting.

Poor compliance:

Antibiotic cycling is in principle the most restrictive of all approaches to antimicrobial stewardship as it involves dictating the clinicians exactly which antimicrobials are to be used in a given time period. Therefore researches done on antibiotic rotation reveals that compliance with the cycling protocol is extremely low. There could be many reasons behind it such as

- Physicians may ignore the protocol and prescribe off-cycle antimicrobials to their patients
- Allergies or toxicity may preclude administration of the on-cycle drug
- The final regimen may be tailored to culture results.

Back end strategies:

Back end strategies include antimicrobial review methods and providing timely feedback.

Antimicrobial review methods:

Though difficult to perform, but it is the most effective strategy to implement AMSP. This is done at two stages. First, during the clinical rounds, an exhaustive and thorough intra unit review of various aspects of antimicrobial use can be carried out. This should be further reviewed (for a second opinion) during stewardship rounds which should be carried out by AMS team members. The various aspects of antimicrobial use which can be reviewed are

- Indication for antibiotic and compliance with policy
- Appropriateness of the antibiotic choice, dose, route and duration
- Duplicative therapy [potential overlapping spectra]
- Review of directed therapy based on microscopy or PCR, biomarkers or other rapid tests.
- Timely de-escalation or escalation based on culture and susceptibility report.
- Potential for conversion from IV to oral route.
- Requirement for therapeutic drug monitoring
- Any antibiotic related adverse events
- Any potential drug interactions
- Drug allergy if any
- Requirement for renal adjustment
- Need for extended infusion

Back-end strategies, although more labour-intensive, are:

- More widely practice.
- More easily accepted by clinicians.
- Provide a higher opportunity for educating and training the health care professionals.
- They probably provide a more sustained impact of improving the overall quality of antimicrobial prescribing [Chung et al 2013]

Step-6: Educate and train:

Similar to any other health care program, AMSP also needs continuous e training, motivation and assessment of the health care providers. Developing antimicrobial stewardship 1s a behavioural change within the person. Hence, adequate motivational education MUST to bring in such change.

- **Who should receive education in Hospitals** -Every stake holder should be educated on rational use of antimicrobials.

  - Medical practitioners (physicians and surgeons), pharmacists and nurses should be educated about AMSP.
  - AMSP should be brought in as a part of undergraduate, internship and post graduate curriculum.
  - Educating patients and the general public is also important and it may indirectly support hospital education efforts. The following aspects should be addressed.

    - ♣ General hygiene
    - ♣ Hazards of Antibiotic use without prescription
    - ♣ Discouraging over the counter sale

- **Content of education** -Content should be adapted to each profession.

  - Basic knowledge of infection management,
  - Basic microbiology
  - Importance of prudent prescribing in tackling AMR
  - Best practices for prescribing to support safe and effective prescribing administration and monitoring of antimicrobial therapy.

    - **Who should deliver the training-** It is usually delivered by the AMSP team members. However, the administrators should take part active role and address the audience time to time to increase the seriousness of the training.

- **Evaluation process -**Without assessment, no educational training can be effective. Various assessment tools can be used for the competency assessment of the trainee time to time.

  - Attendance forms
  - Completion certificates
  - Questionnaires
  - Case scenario based test

EVALUATION OF ANTIMICROBIAL STEWARD PROGRAMME

Measurement of prescribing is essential to evaluate the impact of stewardship intervention on clinical practice and demonstrate benefits for patients. It is said that "If you cannot measure it, you cannot improve it". There are various ways the impact of AMSP is evaluated (table 5).

Table 5 – Methods for evaluation of AMSP

1.Policy adherence indicator (process indicator)
- Antimicrobial Stewardship Audit

2.Antibiotic Usage-outcome indicator
- Antibiotic usage surveillance (DDDs and DOTs)

3.Antimicrobial resistance –outcome indicator
- AMR surveillance – Manual and WHONET

4.Clinical outcome indicators-
- Morbidity and mortality

5.Financial outcome indicators

Policy Adherence outcome indicators

Antimicrobial Stewardship Audits:-

Antimicrobial stewardship audits (ward rounds) should be done to monitor the adherence to antibiotic policy of the hospital. The members of AMS team members should carry out this audit. Antibiotics Prescription Card should be implemented in the hospital (figure-5). For each patient on antibiotics, this card should be filled and countersigned by the ICU or ward liaison. During the AMS audit rounds, the AMS team will evaluate the correctness filling the card.

The policy adherence outcome indicators include-

a) Antimicrobial prescription card filling adherence rate = No. of cards filled / Total no. of antimicrobial prescriptions given in the same period X 100

(b) De-escalation adherence rate = No. of times de-escalation done after the culture sensitivity report! No. of possible de-escalations indicated in the same period X 100

(c) Handbook adherence rate = No. of times antimicrobials prescribed according to antimicrobial stewardship pocket guide, SVIMS/ Total no. of antimicrobial prescriptions given in the same period X 100

(d) Percentage of culture sent before administration of antimicrobials = No. of times blood culture sent before administration of antimicrobials / Total no. of blood culture sent in the same period X 100

(e) Timely cessation of antibiotics given for surgical prophylaxis.

Antimicrobial usage outcome indicators

This will be calculated based on DDD (Defined Daily Dose) and Days of Therapy (DOT).

(a) No of Defined Daily Dose (DDD)-

Defined Daily Dose (DDD) is the average maintenance dose per day for a drug used for its main indication in adults.

Therapeutic dose should not be used for calculating antibiotic usage because it varies between the persons depending upon the weight, disease, associated factors such as renal adjustment etc. Hence, DDD is the best indicator to calculate the antimicrobial consumption. Every antimicrobial has a WHO assigned DDD WHOCC- ATC/DDD Index which should be used for calculating the DDDS (table 6).

No of DDDs = Therapeutic dose (No. of Tablets used X gm per tablet) / WHO defined DDD of the antimicrobial.

DDDs per 100 patient days: No of DDDs used in an ICU in a period/ Total patient days of the ICU in the same period (sum of occupied beds daily) X 100

Table-6: Antibiotics, their therapeutic dose and Defined daily dose (DDD)

	ATC Index	Antibiotics	Antibiotic Name	Therapeutic dose	DDD
J01C		Beta- lactam antibacterials (Pn)			
	J01CE01		Crystalline (Benzyl) Penicillin	2 lakh units QDS	3.6g
	J01CR05		Piperacillin plus Tazobactam	4.5 gm QDS	14g
J01D		Other Beta- lactam antibacterials			
	J01DH02		Meropenem	1 gm TDS	2g
	J01DC	2nd generation cephalosporin			
	J01DC02		Cefuroxime		0.5g(o)3g(p)
	J01DD	3 rd generation cephalosporin			
	J01DD04		Ceftriaxone	1 gm BD	2g
	J01DD12		Cefaperazone	2gm BD	4g

			Sulbactum		
	J01DD08		Cefixime	1 gm BD	0.4 g
	J01DD02		Ceftazidime	1 gm TDS	4 g
	J01DD01		Cefotaxime	1 gm BD	4 g
J01FA		Macrolide and Lincosamides			
	J01F		Azithromycin	250 mg OD	0.3 g
S01AA26		Amino glycoside			
	J01G		Amikacin	750 mg OD	1 g
J01GB03		Gentamicin			0.24g
	J01MA	Fluoroquinolones			
	J01MA02		Ciprofloxacin	200 mg BD	1 g(o) 0.5 g (p)
	J01MA12		Levofloxacin	750 mg OD	0.5 g
	J01MA14		Moxifloxacin	400 mg OD	0.4g
	J01MA01		Ofloxacin	400 mg BD	0.4 g
		Others			
	J01XB01		Colistin	2 million units TDS	3 MU
	J01XA01		Vancomycin	2 gm BD	2g
	G01AF01		Metronidazole	0.5g TDS	0.5g

(b) Days of Therapy (DOT per 100 patient days)-

Days of Therapy (DOT) per 100 patient days-

Total days of therapy of an antimicrobial in an ICU in a period/ total patient days of the ICU in the same period (sum of occupied beds daily)*100

Antimicrobial resistance outcome indicator

AMR Surveillance is the key to generate local antibiogram pattern of the hospital which can be used to monitor the trend of AMR. Department of microbiology should carry out the surveillance to generate data on AMR and communicate the clinicians time to time.

AMR can be generated at various levels

a. Location wise AMR pattern (ward/ICU/OPD wise)

b. Specimen wise AMR pattern

c. Overall AMR pattern of the hospital. .

There are two methods by which AMR Surveillance is carried out.

a. Manual data entry and analysis by using Microsoft excel.

b. WHONET

Clinical outcome indicators

These include the parameters to measure the infection related morbidity and mortality.

a. **Morbidity indicators.-**

i. Length of stay in ICU
ii. Surgical site infection (SSI) rate
iii. Rate of occurrence of complication due to sepsis e.g. organ failure
iv. Rate of occurrence of readmission within 30 days
v. Ward to ICU transfer rate
vi. Antibiotic-related toxicity (e.g. amino glycoside) rate
vii. Rate of CD1 (C. difficile infection)

b. **Mortality indicator-**

1. Death due to sepsis by sepsis score
2. Standardized Mortality Rates (SMRs)

Financial outcome indicators-

a. Antibiotic cost per patient day-Antibiotics used per day in an ICU X cost of the antibiotics
b. Antibiotic cost per year-Antibiotics used in an ICU for the whole year X cost of the antibiotics
c. Antibiotic cost per admission-Antibiotics used in the ICU in a given period X cost of the antibiotics / no. of admissions in the same ICU during the period X 100.

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Policy on Laundry & Linen management

Purpose: .

1. To provide linen free of dirt, soils and stains to all User Departments.
2. To monitor and enforce controls necessary to prevent spoilage (wear & tear due to washing) of linen and reduce the frequency of linen turn over by increasing their life period.
3. To maintain record of effectiveness of cleaning, disinfecting and turnover.
4. To stay updated regarding developments in the field in the interest of efficiency, economy, accuracy and provision of better patient care.
5. To undertake studies for improvement of clean practices and processing methods to provide supplies economically.
6. To develop a cost effective program by cost analysis of personnel, supplies and equipment.

Scope:

- To provide, adequate supply of clean linen conforming to highest standards of cleanliness and hygiene immediately and constantly available for routine and emergency use from a central place to all the hospital departments
- To reduce the overall cost and contributing towards the efficient and effective supply of linen to all departments of hospital.

Laundry and Linen Management:

Every hospital should have a policy for providing hygienic clean linen for patients and staff efficiently. It should also address prevention infection or injury in patients and health cafe staff involved in the use, handling or laundering of hospital linen.

AIM: The aim of the Laundry Department is to provide all the hospital departments served, adequate supply of clean linen conforming to highest standards of cleanliness and hygiene immediately and constantly available for routine and emergency use from a central place thus reducing the overall cost and contributing towards the efficient and effective supply of linen to all Hospital Departments.

OBJECTIVES:

The objectives of the Laundry Department are as follows:

1. To provide linen free of dirt, soils and stains to all User Departments.
2. To monitor and enforce controls necessary to prevent spoilage (wear & tear due to washing) of linen and reduce the frequency of linen turn over by increasing their life period.
3. To maintain record of effectiveness of cleaning, disinfecting and turnover.
4. To stay updated regarding developments in the field in the interest of efficiency, economy, accuracy and provision of better patient care.
5. To undertake studies for improvement of clean practices and processing methods to provide supplies economically.
6. To develop a cost effective program by cost analysis of personnel, supplies and equipment.

There are 3 types of linens.

Used linen	Fouled and blood stained linen from patients Not considered to have infections organisms or communicable diseases.
Infectious linen	Linens from patients known to have suffered from infectious diseases such as MRSA/MDROs, BBVs or any other infections. High-risk group - diseases are transmitted through a low infectious dose of organisms. e.g., *Escherichia coli* 0157, shigellosis, etc. Infested linen — Linen of patients infested with lice. Fleas. Notify laundry to ensure special arrangements are instigated.
l heat labile linen	Linen which is made from fabrics likely to be damaged by the normal heat disinfection process, usually personal clothing
Note: Category 4 pathogens - Linens must be bag in yellow biomedical waste bap and are sent for incineration e.g. anthrax, viral hemorrhagic fevers	

INFECTION CONTROL MEASURES AT LAUNDRY

General considerations

Laundry area designed in a way so as to prevent dissemination of organisms onto finished textiles.

- All laundry areas must have impermeable floor surfaces.

- The ventilation should include adequate filtration, air exchange rate (5 - 10 per hour) and exhaust.
- *Two area:* The laundry should be partitioned into two separate areas -
  - a "dirty" area for receiving and handling the soiled laundry and
  - a "clean" area for processing the worked items and textile storage.

- *Functional separation* may be achieved by

  - physical barriers or
  - negative air pressure systems in the soiled linen area or
  - positive air flow from the clean area to the soiled linen area
  - Use and maintain laundry equipment according to manufacturers' instructions.

- Damp textiles should not be left in machines overnight.
  - All personnel involved in the collection, transport, sorting, and washing of soiled linen - *adequately trained and wear appropriate PPE.*
  - *HCWs* must cover all exposed skin lesions with waterproof plasters and wear appropriate gloves.
  - ♣ Gloves used for the task of sorting laundry must be of sufficient thickness – Minimize sharps injuries.

- Adequate hand washing facility must be there.
  - Inadvertent disposal of objects (sharps and non-laundry items such as surgical instrunents)- should be removed at the point of packaging.

Laundry bags

- Single bags of sufficient tensile strength must be used
- Leak-proof containment is needed-if the laundry is wet and can soak through a cloth bag.
- Only two third of the bag should be filled to allow secure closure
- Clearly identified with labels, indicating the point of origin.
- Colour-coding should meet the local policy if possible.

Infected linen should be placed in an impervious bag that can be emptied into a washing machine with no or minimal handling and the bag either decontaminated in the washing process or disposed of as infectious health care waste.

Segregation

Infectious linen must he segregated at the point of generation, not at laundry site.

Sorting

- Handle the linens with care at all times.

- Place the linens into bags at the point of generation as soon as possible.
- Bags must be securely tied to prevent leakage.
- Rinsing of soiled laundry at the point of generation should not be done.
- Both soiled and infectious categories of linen undergo identical thermal disinfection – The designation of some linen as 'infectious' is only to minimize workers" contact with it.

All used linen shall be considered contaminated and shall be bagged at the location of use before being taken to laundry.

A. Soiled linen:

- ϖ Soiled linen shall be collected in the designated container and taken to laundry
- ϖ Designated container shall be covered during transport of soiled linen.
- ϖ Cloth liners /containers shall be washed daily
- ϖ Dirty utility room shall be swept daily and washed /Mopped with a detergent/Disinfectant weekly and whenever visibly soiled
- ϖ Soiled linen shall be handled as little as possible and with minimum agitation, in order to prevent gross microbial contamination of the air and of persons handling the linen
- ϖ All soiled linen shall be bagged at the location of use. Soiled linen shall not be sorted in-patient care areas.
- ϖ Bags containing soiled linen shall be tied before being taken to laundry in order prevent spillage
- ϖ All linen that is contaminated with blood, excreta or other body fluids shall be placed in designated laundry bags Personnel shall wear protective clothing, including gloves and gowns/aprons when handling soiled linen.
- ϖ Employees collecting linen at the laundry shall also wear heavy-duty gloves and a gown.

- ϖ Hands shall be washed after gloves are removed.
- ϖ Staff shall be instructed in the principles of personal hygiene, including frequent hand washing

B.Clean linen:

□□Hand washing for 10-15 seconds, with attention to nails and areas fingers is mandatory before handling clean linen.

□□Clean linen shall not be handled more than necessary in order to minimize contamination.

□□Any linen dropped shall be considered soiled

□□Covered linen carts shall be used to transport clean linen to the units

□□Clean linen shall be stored in a clean, dry area.

Facilities:

□□□□Hand washing facilities are available to all employees in the linen area

□□□□Barriers to protect employees from blood, body fluids, secretions and excretions are located in the laundry area. Employees shall be informed of the location and of barriers at the time of orientation to the unit.

- ϖ Carts must be cleaned before transporting clean linen

C.Patient linen

- ϖ Bed linen is to be changed daily and whenever soiled with blood or body fluids.
- ϖ Patient's gown is to be changed every day and whenever soiled with blood or body fluids. Dry dirty linen is to be sent to the laundry for regular wash.

Transport

• Clean and used linen should be transported in separate dedicated closed containers, bag. trolley and lifts. They must never be transported together.

• Soiled linen in begs can he transported by cart or chute but loose, soiled pieces of laundry should not be tossed into chutes.

• Trolleys should also be cleaned and disinfected in following situations:

- After any spillage
- After transportation of dirty laundry
- Through cleaning with soap and water at least weekly

• Same vehicle can be used to both collect and deliver dirty and clean linen with internal separation

Storage

• Clean linen should be stored in a clean area of the ward in closed cupboard.

• It should be stored separate from unsoiled linen

• Must not be stored within the sluice or bathroom.

Disposal of Linen

• The linen that required to be dispose oft-must be disinfected and duly washed as soiled linen described below.

• After drying, the linen records are presented to the condemnation committee.

• After due certification from the committee such linen should be shredded or cut in small pieces and then dispose off in yellow bag to bio-medical waste collector for final disposal.

Laundry process

Linen and clothing used in hospitals on laundering are rendered free of vegetative pathogens (hygienically clean), but they are not sterile.

The washing cycle used for laundering is of various types:

• Typical thermal washing cycle

• Low temperature cycle

• Dry cleaning

• Home washing machines

Typical thermal washing cycle

The thermal washing machines used for laundering may he of two types- i)Washer/ extractor units. ii) Continuous batch machines.

The washing cycle involves three main phases, i.e, pre-wash, main wash (disinfection cycle) and rinse cycle.

•Pre-wash: Linens are washed with water with soap and detergent, the antimicrobial action is due to cleaning with soap and detergent, dilution and agitation/shaking during the pre-washing cycle.

•Main wash (heat disinfection cycle)- Minimum holding time is 65°C for 10 min (or 7I°C for 3 min). Additional time should be given to allow mixing and heat penetration.

•Rinse cycle- Removes the soap and detergents present if any.

Low-temperature wash

Low-temperature wash is useful for – heat labile fabrics, to reduce hot water consumption and thereby saving cost [laundry is the largest users (50-75%) of hot water in hospitals]

• The steps are same as thermal washer except that sodium hypochlorite is used for disinfection in the washing machine instead of heat_

• The amount of bleach should be carefully monitored and controlled. Usually recommendation is 150 ppm available chlorine,

Dry cleaning

• The dry cleaning process involves use of organic solvents such as perchloroethylene to remove soil from heat labile linen that might be damaged in thermal washing or detergents.

• Dry cleaning should not be used routinely because it is relatively ineffective in reducing the numbers of microorganisms on contaminated linen.

Home washing machine

• It is suitable for staff uniforms as these are only used to identify staff and not as personal protective equipment.

• If staff uniforms do become grossly contaminated - washed with used or infected* hospital linen as appropriate.

Drying and ironing

Drying and ironing provides an additional antimicrobial activity.

• Drying of the linen is done either in a drier (preferable) or in sun

• Heavy duty washers/ driers are recommended for drying.

• Dryer temperatures and cycle times are determined by the type of materials in the fabrics.

• Man-made fibers (i.e., polyesters) require shorter times and lower temperatures.

• Ironing is done either by manual or by automated systems (preferable).

Monitoring

Routine microbiological sampling of cleaned linen is not recommended.

• The efficiency of the disinfection cycle should be checked only during following situations.

- When commissioning new machines. at regular intervals (every 6 weeks) and
- During outbreak investigation - if epidemiological evidence suggests linen or clothing as a vehicle for disease transmission.

• Sampling techniques include

- Aseptically macerating the fabric into pieces and adding these to broth media or
- Using contact plates for direct surface sampling.
- When evaluating the disinfecting properties of the laundering process specifically, placing pieces of fabric between two membrane filters may help to minimize the contribution of the physical removal of microorganisms.
- Enterococci can be used as bioindicator to onitor the efficacy of laundry process.

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Policy on Kitchen sanitation and food handling issues

Purpose:

- To ensure that food provided to patients and staff in a safe and hygienic manner.
- To supply food in a hygienic way
- To identify food safety hazards, know which steps in the processes are critical for food safety.
- To ensure that safety controls are in place maintained and controlled.

Scope:

- Document of standard precautions
- Conduct training on personal hygiene, food safety and food-borne diseases .
- Surveillance and monitoring for food born infections like salmonella, entmoeba histolytica and etc.
- Develop action plan and function accordingly.

SVIMS hospital conducts periodic screening of kitchen workers and food handlers for carriage of parasites and *Salmonella.*Typhi every six months or if the staff rejoins after leave of 15 days or more.

GENERAL RULES OF FOOD HYGIENE

Food services chain consists of:
Receiving raw food
Storing
Food preparation (cutting/ sorting, cooking)
Direct serving / chilling/ heat holding/ reheating before serving
Strict standards pertaining to hygiene should be maintained during all the stages Kitchen stew.

- Should be trained about personal hygiene, food safety and food-borne diseases
- Should wear clean clothes and change work clothes at least once daily.
- They should wear protective aprons and keep their hair covered while preparing food
- They should clean their hands, face and hair and trim their nails

- Staff should be instructed not to touch their nose, lips and hair while preparing food.
- Must wash hands before handling food, after going to the toilet, after handling raw food and after coming in contact with unclean equipment] work surfaces.
- They must use hot water with soap (preferably liquid) and dry hands with clean dry cloth towels, fresh paper towels or by air drying. They may use an antibacterial soap during an outbreak.
- Food should be handled using preferably disposable gloves.
- All injuries and cuts should be covered with waterproof tapes.
- Workers suffering from acute diarrhea, enteric fever, draining abscess or skin infections should not handle food and such episodes should be bought to the notice of the medical officer.
- Frequent training of the staff and inspection of the kitchen hygiene should be carried out by the infection control team

Kitchen infrastructure:

- ¬ Proper maintenance of refrigerators and freezers is needed with checking and recording of their temperatures daily.
- ¬ Adequate supply of clean and potable water to the kitchen should be ensured along with adequate hand washing facility.
- ¬ Preparation area should have the provision of sink with running hot and cold water, working drainage system and windows with screens.
- ¬ Kitchen should be a **no smoking area.**
- ¬ There should be adequate storage area with adequate fire protection and sufficient ventilation.
- ¬ Entry to the food preparation area should be restricted.

Preparation of food:

- ¬ Serving to be done as soon as possible after preparation.

  Preparation of raw and cooked food should have different designated areas to prevent cross contamination.

Never process cooked and uncooked meat using the same machines.

Maintain the temperature and refrigeration requirements for both raw and cooked foods for food protection.

Serve cooked perishable foods within two hours of preparation and dispose of thereafter.

Food storage and distribution:

- After cooking, all the food to be stored should be immediately cooled.
- All food items should be kept in covered containers and labeled with date and content.
- All food items should be within the expiration dates.

Storage of all food items should be away from the walls and at least 6 inches above the floor level.

- No storage of food items to be done with contaminated materials, clinical specimens or medical products such as drugs, vaccines and blood.
- Only trained staffs should distribute food in dedicated, clean trolleys.

'Protect food from vectors using nets, clean cloth or covers.

Maintain and wash trolleys daily or more frequently if soiled.

Cleaning, inspection and supervision:

' Strict protocols regarding cleaning and maintenance should be made and followed

‘ The entire kitchen area should be dust free and the work areas and food storage areas clean and well maintained

' Clean and disinfect the working areas and all utensils after each use. All equipment to be cleaned daily and kept in a way that the area around them can be cleaned daily

‘ Walls and ceiling should have smooth and impermeable surfaces

' Detergent and hot water can be used for cleaning. A clean cloth should be used and

changed daily Screening of kitchen workers:

Surveillance must be conducted biannually for carriage of MRSA and Salmonella

Kitchen Hygiene

1. W**ash your hands**
   - **Thoroughly using hot water and soap.**
   - **Before commencing any food preparation.**
   - **After visiting a toilet.**
   - **After blocking a cough or sneeze into a hand.**
   - **After rubbing hair, nose, mouth, ears, eyes etc.**
   - **After touching raw foods.**

2. **Cook properly**
   - Cover all cuts or sores in the skin with water proof dressing.
   - Do not handle food with hands unless absolutely necessary. Use clean tongs, forks or ladles that can be easily washed.
   - Where a head cover and clean clothes at all times.
   - Do not place raw foods in contact with cooked foods.
   - Food should be properly cooked to avoid risk of harmful bacteria being ingested which can cause food poisoning.

3. **Storage**

   - Correct storage of food in kitchens is as important as correct cooking.
   - All frozen foods must be thawed in a refrigerator.
   - Do not use any canned food which is leaking.
   - Ensure rotation of food stuffs being stored.
   - Use no food which exhibits signs of the presence of insects or rodents or with objectionable odours.
   - Always cover food because food left out in the open is vulnerable to bacteria.

4. **Washing fruits and vegetables**

   - When handling fresh fruits and vegetables it is always advisable to wash them before using them.
   - Washing fruits and vegetables can help remove harmful germs and bacteria from the foods surface.

5. **Cleaning up**

   - **Ensure that all plates and eating utensils are washed regularly.**

- After cooking, cleaning up is very important.
- The kitchen chopping board must be cleaned after every use.
- Washing and wiping down of kitchen equipment must be done regularly to reduce the risk of cross-contamination dramatically.

Policy on appropriate engineering control to prevent infections

Purpose:

- To design patient care areas optimally.
- To maintain records related to infection control practices.
- To maintain HEPA filters, equipment and also water resources.

Scope:

- To monitor periodic checking of patient care areas, operating rooms.
- To monitor periodic checking of HEPA filters and equipment
- To monitor periodic checking of chlorination and also water sample testing .

The organization has appropriate engineering controls to prevent infections*:

Engineering Controls to Prevent Infection:

SVIMS adopts appropriate engineering control to prevent infections.

1. The hospital patient care areas are designed in such a manner to ensure optimum bed spacing.
2. Operating rooms are provided with HEPA filter, to ensure double filtration of air.
3. Periodical checking of water resources
4. Periodical checking and maintenance of equipment, A/C ducts, replacement of filters.
5. Periodical checking, replacement/ repair of plumbing and sewer lines.
6. Machinery and equipment should be checked, cleaned and repaired routinely.
7. Urgent repairs should be carried out at the end of the day's list.
8. Air conditioners and suction points should be checked, cleaned and repaired on a weekly basis.
9. Preventive maintenance on all theatre equipment to be carried out weekly and major work to be done at least once every year.

1. Bed Spacing in SVIMS: The bed space in all wards in between two beds or space between the centres of the two adjacent beds is 02 to 03 feet/1.5 meters in all wards.

ICU and Recovery Rooms: The centre of two adjacent beds 04 – 5feets. In communicable decease like TB ward, centre of two adjacent beds space is 06feets. Generally in SVIMS we are maintaining 02 to 03 feet/01.5meters beds space in all wards.

In case of any emergencies like infectious/ contagious/communicable deceased patients were isolated. In some areas like RICU, Emergency Medicine we are maintains the bed space distance of 03 feet from the wall to the head end of the cot.

Policy on Housekeeping procedures

Purpose:

- To focus primarily on safety of the patient, staff and visitors.
- To reduce the spread of infections.

Scope:

- Training on infection control practices related to housekeeping
- Documentation of housekeeping checklist
- To review infection control practices related to housekeeping as often as required to keep abreast of changes in the health care.

House keeping

i. House Keeping in Wards

A patient admitted to the hospital can develop infection due to bacteria that survive in the environment. Therefore, it is important to clean the environment thoroughly on a regular basis. This will reduce the bacterial load and make the environment unsuitable for growth of micro-organisms.

- The floor is to be cleaned at least twice times in 24 hours. Detergent and copious amounts of water should be used during one cleaning. Ecoshield may be used to mop the floor for the remaining times.
- The walls are to be washed with a brush, using detergent and water once a week
- High dusting is to be done with a wet mop
- Fans and lights are cleaned with soap and water once a month.
- All work surfaces are to be disinfected by wiping with Ecoshield and then cleaned with detergent and water twice a day.
- Cupboards, shelves, beds, lockers, IV stands, stools and other fixtures are to be cleaned with detergent and water once a week.
- Curtains are to be changed once a month or whenever soiled. These curtains are to be sent for regular laundering. In certain areas, eg. Transplant units and ICUs, more frequent changes are required.
- Patient's cot is to be cleaned every week with detergent and water. 1% hypochlorite to be used when soiled with blood or body fluids. In the isolation ward, cleaning is done daily.
- Store rooms are to be mopped once a day and high dusted once a week.

- The floor of bathrooms is to be cleaned with a broom and detergent once a day and then disinfected.
- Toilets are cleaned with a brush using a detergent twice a day (in the morning and evening). Disinfection and stain removal solution may be used.
- Wash basins are to be cleaned every morning
- Regular A/C maintenance is required. The A/C section should draw up a protocol for this.

ii. Patient linen

- Bed linen is to be changed daily and whenever soiled with blood or body fluids.
- Dry dirty line is to be sent to the laundry for regular wash.
- Line soiled with blood or body fluids, and all linen used by patients diagnosed to have HIV, HBV, HCV and MRSA, is to be decontaminated by autoclaving before being sent to the laundry.
- The hospital does not provide any patient gown (except for patient prepared for surgery) however patient and their relatives are encouraged to change the patients clothes every day.

Iii.Miscellaneous items

Kidney basins, basins, bed pans, urinals, etc to be cleaned with detergent and water and disinfected with 7% Lysol.

HOUSE KEEPING IN THE OPERATION THEATRE

Theatre complex should be absolutely clean at all items. Dust should not accumulate at any region in the theatre.

Soap solution is recommended for cleaning floors and other surfaces. Operating rooms are cleaned daily and the entire theatre complex is cleaned thoroughly once a week.

Before the start of the 1st case

Wipe all equipment, furniture, room lights, suction points, OT table, surgical light reflectors, other light fittings, slabs etc with soap solution. This should be completed at least one hour before the start of surgery.

i.Linen & gloves

Gather all soiled linen and towels in the receptacles provided. Take them to the service corridor (behind the theatre) and place them in trolleys to be taken for sorting. The dirty linen is then sent to the laundry. Use gloves while handling dirty linen.

ii.Instruments

Used instruments are cleaned immediately by the scrub nurse and the attender. Reusable sharps are decontaminated in Lysol / hypochlorite and then washed in the room adjacent to the respective OR by scrubbing with a brush, liquid soap and vim. They are then sent for sterilization in the CSSD. After septic cases the instruments are sent in the instrument tray for autoclaving. Once disinfected, they are taken back to the same instrument cleaning area for a manual wash described earlier. They are then packed and re-autoclaved before use.

iii. Environment

Wipe used equipment, furniture, OR table etc., with detergent and water. If there is a blood spill, disinfect with sodium hypochlorite before wiping.

Empty and clean suction bottles and tubing with disinfectant.

iv. After the last case

The same procedures as mentioned above are followed and in addition the following are carried out.

- Wipe over head lights, cabinets, waste receptacles, equipment and furniture with ecosheild.
- Wash floor and wet mop with liquid soap and then remove water and wet mop with 2% Lysol solution.
- Clean the storage shelves scrub & clean sluice room.

v. Weekly cleaning procedure

- Remove all portable equipment.
- Damp wipe lights and other fixtures with detergent.
- Clean doors, hinges, facings, glass inserts and rinse with a cloth moistened with detergent.
- Wipe down walls with clean cloth mop with detergent.
- Scrub floor using detergent and water or 2% Lysol
- Stainless steel surfaces – clean with detergent, rinse & clean with warm water.
- Replace portable equipment: Clean wheel castors by rolling across toweling saturated with detergent.
- Wash (clean) and dry all furniture and equipment (OT table, suction holders, foot & sitting stools, Mayo stands, IV poles, basin stands, X-ray view boxes, hamper stands, all tables in the room, holes to oxygen tank, kick buckets and holder, and wall cupboards)
- After washing floors, allow disinfectant solution to remain on the floor for 5 minutes to ensure destruction of bacteria (2% Lysol)

Before the start of the 1st case

Wipe all equipment, furniture, room lights, suction points, OT table, surgical light reflectors, other light fittings, slabs etc. with soap solution. This should be completed at least one hour before the start of surgery.

a. Linen & gloves

Gather all soiled linen and towels in the receptacles provided. Take them to the service corridor (behind the theatre) and place them in trolleys to be taken for sorting. The dirty linen is then sent to the laundry. Use gloves while handling dirty linen.

b. Instruments

Used instruments are cleaned immediately by the scrub nurse and the attender. Reusable sharps are decontaminated in Lysol / 1% hypochlorite and then washed in the room adjacent to the respective OT by scrubbing with a brush, liquid soap and vim. They are then sent for sterilization in the CSSD. After septic cases the instruments are sent in the instrument for autoclaving. Once disinfected, they are taken back to the same instrument cleaning area for a manual wash described earlier. They are then packed and re- autoclaved before use.

c. Environment

Wipe used equipment, furniture or table etc., with **detergent and water**. If there is a blood spill, disinfect with 1% sodium hypochlorite before wiping.

Empty and clean suction bottles and tubing with disinfectant.

d. After the last case

- The same procedures as mentioned above are followed and in addition the following are carried out.
- Wipe over head lights, cabinets, waste receptacles, equipment, furniture with disinfectant like rapid Sterilium/Incidure etc.
- Wash floor and wet mop with liquid soap and then remove water and wet mop with Lysol solution.
- Clean the storage shelves, scrub & clean room.

Weekly cleaning procedure

- Remove all portable equipment.

- ϖ Damp wipe lights and other fixtures with detergent.
- ϖ Clean doors, hinges, facings, glass inserts and rinse with a cloth moistened with detergent.
- ϖ Wipe down walls with clean cloth mop with detergent.
- ϖ Scrub floor using detergent and water or Lysol.
- ϖ Stainless steel surfaces - clean with detergent, rinse & clean with warm water.
- ϖ Replace portable equipment: Clean wheel castors by rolling across toweling saturated with detergent.
- ϖ Wash (clean) and dry all furniture and equipment (OT table, suction holders, foot & sitting stools, Mayo stands, IV poles, basin stands, X-ray view boxes, hamper stands, all tables in the room, holes to oxygen tank, kick buckets and holder, and wall cupboards)

After washing floors, allow disinfectant solution to remain on the floor for 5 minutes to ensure destruction of bacteria.

HOUSE KEEEPING POLICY AT SVIMS

General rules for Housekeeping at SVIMS

3. Man power must be adequate for regular cleaning of walls,ceiling ,fan once in month.
4. Manpower to supervise housekeeping works.
5. Adequate base materials (buckets, detergent, disinfectant) should be made available to maintain a proper housekeeping policy.
6. Washing of the mop should be done in between cleaning.
7. Fumigation is not recommended on a routine basis, It is done only during outbreak, after new constructions.
8. Personal protective equipment must be provided to the housekeeping workers during work
9. Use a single damp cloth per patient. If the damp cloth is reusable soak the damp cloth in detergent/ disinfectant and dry before use.
10. Damp dusting rather than dry dusting/sweeping shall be performed.
11. Wet mopping should be done by double bucket technique which extends the life of the solutions because fewer changes are required. When a single bucket is used solutions should be frequently changed because of increased bioload.

Classification of housekeeping areas:

The cleaning procedure adopted at SVIMs which is described in the table below is dependent on the type of area. For housekeeping purpose, SVIMS has been divided into the following zones.

Very High Risk areas	Outbreak in high risk areas
High Risk Areas	IC?U, HDU, burns unit, Transplant units, operating suits, post op wards, laboratories
Moderately areas	General wards, OPDs
Low risk area	Rehabilitation centres, long term care, office based

CDC recommends using disinfectant for environmental surfaces of critical area and detergent for non-critical area except when the patient is on isolation where disinfectant is preferred. The reason is explained in table below.

The following detergents/disinfectants are used for housekeeping at SVIMS

1. Detergent- e.g. Soap chips/liquid soap

2. Disinfectants

- Lizol (Benzalkonium chloride 80 %)- Detergent
    - Floor and bathroom surface: use one capful in half a bucket of water. Gently mop the surface. No need to rinse (4 liters).
    - Kitchen: Use undiluted. Apply on dirty area and leave for ten min and rinse
- Cidex (glutaraldehyde 2% plus Benzalkonium chloride 5%)- Disinfectant

Table: Comparison of disinfectant and detergents for use on noncritical environmental surfaces

Features	Disinfectants	Detergents
For surfaces contaminated by blood and other potentially infective material	More effective	Less effective
In reducing microbial load on floors	More effective	Less effective
Antibiotic- Resistance	Yes	No
Cost	High	Lower costs
Odour	Unpleasant	More aesthetically pleasing floor
Occupational exposure	Side effects can occur	No side effect
Environmental impact (aquatic or terrestrial)issues	May be seen	No

with disposal		
CDC recommendation		
For all critical area Non critical area, if patients on isolation precautions	Recommended by CDC	Not recommended
For non- critical area	Advantage of using a single product for decontamination of noncritical and critical area	• Non critical surfaces contribute minimally to endemic HAIs • No difference in HAI rates when floors are cleaned with detergent versus disinfectant

Table: Housekeeping policy at SVIMS

(Adapted from National Patient? Safety Agency, UK,April 2007 and Local policy SVIMS)

ITEMS	VERY HIGH RISK AREA	HIGH RISK AREA	MDERATE RISK AREA	LOW RISK AREA	METHOD
Bed	Clean frame daily	Clean frame daily	Clean frame daily	N/A	Detergent Detergent + disinfectant for MDRO
	Clean underneath weekly	Clean underneath weekly	Clean underneath weekly		
	Clean whole on discharge	Clean whole on discharge	Clean whole on discharge		
Bed rails	Clean twice daily & after discharge	Clean daily & after discharge	Clean daily & after discharge	Clean weekly & after discharge	Detergent Detergent+disinfectant for MDRO
Bedside table	Clean twice daily& after use	Clean daily &after use	Clean daily	Clean weekly	Detergent Detergent+disinfectant for MDRO
Catheter stand/ bracket	Clean daily & after use	Clean daily & after use	Clean before initial use, after use & monthly	Clean before initial use, after use & monthly	Detergent+disinfectant
Ceiling/High dusting	Spot clean	Spot clean	Spot clean	Spot clean	Detergent/Damp dust Damp cloth

	Monthly	Monthly	Monthly	Monthly	
Chair	Clean twice daily	Clean twice daily	Clean daily	Clean weekly	Detergent Detergent+disinfectant for MDRO
Chair, dental and surrounds	NA	NA	NA	Clean daily & when visibly soiled`	Detergent
Cleaning equipment	Clean after use	Clean after use	Clean after use	Clean after use	Detergent Detergent+disinfectant for MDRO
Chappals	Wash once daily and dry	Wash once daily and dry	NA	NA	Detergent
Clipboard	Clean daily & between patient	Clean daily & between patient	Clean daily & between patient	Clean weekly	Detergent
Commodes	Use Daily twice	Use Daily twice	Use Daily twice	Daily	Detergent and disinfectant
Curtains and blinds (ICU entrance should not have any curtains)	Bed curtains-change or clean weekly upon discharge	Bed curtains-change or clean monthly	Bed curtains-change ot clean 3 months	Bed curtains-change or clean annually	Replace with laundered curtains or steam clean while in place.
	Patient with MDRO or other infectious disease- change bed curtains or clean upon discharge	Patient with MDRO - change bed curtains or clean upon discharge	Patient with MDRO - change bed curtains or clean upon discharge	Patient with MDRO - change bed curtains or clean upon discharge	Replace with laundered curtains or steam clean while in place
Door mat	Weekly/ Whenever it gets fully wet	Weekly/ Whenever it gets fully wet	Weekly/ Whenever it gets fully wet	Weekly/ Whenever it gets fully wet	Detergent and water Dry in sunlight
Elevators	Damp cleaning daily	Damp cleaning daily	Damp cleaning daily	Damp cleaning daily`	Detergent
Door knob/handle/ fridge handle/ general	Clean daily	Clean daily	Clean daily	Clean weekly	Detergent
Drip/ intravenous	Clean contact	Clean	Clean	Clean	Detergent

stands	points after use	contact points after use	contact points after use	contact points after use	Detergent+ disinfectant for MDRO
Fan, patient	Clean weekly & between patient use	Clean weekly & between patient use	Clean weekly once	Clean weekly once	Detergent
Floor, non-slip	Damp mop twice daily	Damp mop twice daily	Damp mop daily	Damp mop daily	Detergent Detergent+ disinfectant for MDRO
Floor, polished	Dust removal by dry mop clean twice daily	Dust removal by dry mop clean twice daily	Dust removal by dry mop clean twice daily	Dust removal by dry mop clean twice daily	Detergent for routine consider electrostatic mops Detergent+ disinfectant for MDROs
Fridge (drug)	Clean weekly	Clean weekly	Clean weekly	Clean weekly	Detergent
Hoist	Clean contact points after use	Clean contact points after use	Clean contact points after use	Clean contact points after use	Detergents
Iv stand & poles	Clean daily & after use	Clean daily & after use	Clean daily & after use	Clean daily & after use	Detergent Detergent+ disinfectant for MDRO
Light switch	Clean daily	Clean daily	Clean weekly	Clean weekly	Detergents
Locker	Clean contact points twice daily	Clean contact points twice daily	Clean contact points twice daily	N/A	Detergent Detergent+ disinfectant for MDRO
Mattress preferable covered by rexin (every 6 months check for durability	Clean weekly & after discharge	Clean weekly & after discharge	Clean weekly & after discharge	Clean weekly & after discharge	Detergent Detergent+ disinfectant for MDRO preferable that entire mattress has waterproof cover
Medical gas equipment	Clean daily	Clean daily	Clean daily	Clean daily	Detergent
Microwave	Clean three times daily	Clean three times daily	Clean daily	Clean daily	Detergent
Case sheet folder	Clean daily	Clean daily	Clean weekly	Clean weekly	Detergent
Oxygen equipment	Clean daily & after use	Clean daily &	Clean weekly &	Clean weekly &	Detergent

		after use	after discharge & before initial use	after discharge & before initial use	
Patient slide/cover bed table	Clean daily & after use	Clean daily & after use	Clean daily & after use	Clean daily & after use	Detergent Detergent+ disinfectant for MDRO
Pillow(water proof cover)	Clean weekly & after discharge	Clean twice monthly & after discharge	Clean & after discharge	Clean monthly & after discharge	Detergent Detergent+ disinfectant for MDRO
Rubber sheet	Change when soiled and between patients	Change when soiled and between patients	Change when soiled and between patients	Change when soiled and between patients	Detergent and dry in sunlight if reusable
Sharps bin trolley	Clean daily	Clean twice weekly	Clean weekly	Clean monthly	Detergent
Shower	Clean daily & after use	Clean daily & after use	Clean daily	Clean daily	Detergent Detergent+ disinfectant for MDRO
Sink (hand washing)	Clean twice daily	Clean daily	Clean daily	Clean daily	Detergent
Surfaces (general) in patient room e.g. .ledges, counter, writing table,, shelf	Clean twice daily & after discharge	Clean twice daily & after discharge	Clean daily & after discharge	Clean weekly& after discharge	Detergent Detergent+ disinfectant for MDRO
Telephone	Clean twice daily	Clean twice daily	Clean daily	Clean weekly	Detergent+ 70% isopropyl alcohol
Toilet	Clean thrice daily	Clean thrice daily	Clean thrice daily	Clean daily OPD-Frequent cleaning	Detergent+disinfectant
Trolley, dressing	Clean before & after use	Clean before & after use	Clean before & after use	Clean before & after use	Clean and wipe with 70 percent isopropyl alcohol impregnated wipes. If contaminated clean with detergent and then disinfect with 70% isopropyl alcohol
Trolley, linen/medicine/food	Clean contact points daily	Clean contact points	Clean contact points daily	Clean contact points	Detergents

		daily		weekly	
	Clean whole trolley weekly	Clean whole trolley weekly	Clean whole trolley weekly	Clean whole trolley weekly	
Trolley, resuscitation	Clean daily	Clean twice weekly	Clean weekly	Clean weekly	Detergent
TV	Clean weekly	Clean weekly	Clean weekly	Clean weekly	Detergent
Walls /windows/doors	Spot clean and regular cleaning once a month	Spot clean and regular cleaning once a month	Spot clean and regular cleaning once a month	Spot clean and regular cleaning once a month	Detergent/Damp dust
Washbowl, patient(each patient should have a dedicated bowl)	Clean between patient use	Clean between patient use	Clean between patient use	Clean between patient use	Detergent Detergent+ disinfectant for MDRO
Waste receptacle	Clean weekly & spot clean as required	Clean weekly & spot clean as required	Clean weekly & spot clean as required	Clean weekly & spot clean as required	Detergent
Wheel chair	Clean daily & after use	Clean daily & after use	Clean weekly & after use	Clean weekly & after use	Detergent

Housekeeping in Intensive Care Unit, Labor Room, and Postpartum Recovery Room:

In addition to routine cleaning it is suggested that thorough cleaning with soap and water should be done once a week. A brush can be used in hard-to-reach areas.

- ¬ Routine Cleaning Procedure.
- ¬ Remove all portable equipment.
- ¬ Damp wipe lights and other fixtures with detergent.
- ¬ Clean doors, hinges, facings, glass inserts, and rinse with a moistened cloth.
- ¬ Wipe down walls with clean cloth and detergent.
- ¬ Scrub floor using detergent and water.

Stainless Steel Surfaces:

- ¬ Wash with detergent, rinse and clean with warm water.
- ¬ Replace portable equipment: clean wheel castors by rolling across towelling saturated with detergent.
- ¬ Wash (clean) and dry all furniture and equipment, such as suction holders, foot and sitting stools, Mayo stands, IV poles, basin stands, X-Ray view boxes, hamper stands, all tables in the room, hoses to oxygen tank, kick buckets and holder, and wall cupboard.
- ¬ After washing floors, allow disinfectant solution to remain on the floor for 5 minutes to ensure destruction of bacteria.
- ¬ Do not remove or disturb delicate equipment.
- ¬ While wiping cabinets, see to it that the solution does not get inside and contaminate sterile supplies.
- ¬ Operating rooms and scrub rooms should never be dry dusted.

Maintenance and Repairs:

- ¬ Machinery and equipment should be checked, cleaned and repaired routinely on Sundays. Urgent repairs should be carried out at the end of the day's list.
- ¬ Air-conditioners and suction points should be checked, cleaned and repaired on a weekly basis.
- ¬ Preventive maintenance on all theatre equipment should be be carried out every Saturday, and major work to be done at least once a year.
- ¬ Surveillance of housekeeping procedures should be done on a routine basis every month by the HIC Nurse as defined by the HICO.

Policy on isolation and barrier nursing

Purpose:

- To reduce the risk of spreading certain infections or antibiotic resistant germs to other patients and staff.
- To protect patients from infection if they have a weak immune system due to disease or taking certain drugs.

Scope:

- Documentation of isolation practices.
- Conduct training on transmission based precautions.
- To provide protective clothing for example gloves, masks, apron and mask (if required) in order to reduce the risk of passing the infection to other patients.
- To develop an action plan and function accordingly

Isolation protocols*

Definition: It is the separation of infected persons from the non-infected persons for the period of communicability under conditions which will prevent the transmission of infection.

When a patient comes with any infectious disease/ Immuno compromised state, the concerned ward staff will inform the ICN and she will arrange the room or if the patient is critically ill admit the patient in side bed allocated for ISOLATAION PATIENTS of the concerned ICU. If the patient can't afford the room patient will be admitted in the isolation room, the patient and the family members will.

Strict Isolation

Strict isolation is an isolation category designed to prevent transmission of highly contagious or virulent infections that may be spread by both air and contact.

Specification for strict isolation

1. Private room is indicated; door should be kept closed.

2. Masks, gowns & gloves are indicated for everyone entering the room.

Contact Isolation

a) Contact isolation is designed to prevent transmission of highly transmissible or epidemiologically important infections (or colonization that do not warrant strict isolation.

b) All diseases or conditions included in this category are spread primarily by close direct contact.

Specification for Contact Isolation

1. Private room is indicated.

2. Masks are indicated for those who come close to the client.

3. Gowns are indicated if soiling is likely.

4. Gloves are indicated for touching infective material.

Isolation Room in Radiotherapy unit-II, SVIMS

Isolation Room for Transplantation cases, SVIMS

Multiple resistant bacterial infection, or colonization (any site) with any of the following

- ϖ Gram-negative bacilli resistant to all aminoglycosides that are tested. Staphylococcus aureus resistant to penicillin.
- ϖ Pneumococcus resistant to penicillin.
- ϖ Haemophilus influenzae resistant to ampicillin (betalactamase–positive) and chloramphenicol.
- ϖ Other resistant bacteria may be included if they are judged by the infection control team to be of special clinical and epidemiological significance.
- ϖ Pediculosis
- ϖ Pharyngitis, infections, infectious, in infants and young children.
- ϖ Pneumonia, viral, in infants and young children.

- ϖ Pneumonia, Staphylococcus aureus or group A streptococcus.
- ϖ Rabies
- ϖ Rubella, congenital and other.
- ϖ Scabies
- ϖ Scalded skin syndrome, staphylococcal (Ritter's disease)
- ¬ Skin wound or burn infection, major (draining and not covered by dressing or dressing does not adequately contain the purulent material) including those infected with Staphylococcus aureus or group A streptococcus.

1) Respiratory Isolation

Respiratory isolation is designed to prevent transmission of infectious diseases primarily over short distances through the air (droplet transmission).

Specifications for Respiratory Isolation

1. Private room is indicated.

2. Masks are indicated for those who come close to the client.

3. Gowns are not indicated.

4. Gloves are indicated if contamination of hands is anticipated.

Requiring Respiratory Isolation

- ¬ Epiglottitis, *Haemophilus influenzae*
- ¬ Erythematic infections
- ¬ Measles
- ¬ Meningitis
- ¬ *Haemophilus influenzae*, known
- ¬ Meningococcal, known or suspected
- ¬ Meningococcal pneumonia
- ¬ Meningococcemia
- ¬ Mumps
- ¬ Pertussis (whooping cough)
- ¬ Pneumonia, *Haemophilusinfluenzae,* in children (any age)

2) Tuberculosis Isolation (AFB Isolation)

- Tuberculosis isolation (AFB isolation) is an isolation category for clients with pulmonary tuberculosis who have a positive sputum smear or a chest film that strongly suggests current (active) tuberculosis. Laryngeal tuberculosis is also included in this isolation category.

Specification for Tuberculosis Isolation (AFB Isolation)

1. Private room with special ventilation is preferred; door should be kept closed.

2. Masks are indicated only if the client is coughing and does not reliably cover mouth.

3. Gowns are indicated only if needed to prevent cross contamination of clothing.

4. Gloves are indicated if contamination of hands is anticipated.

3) Enteric Isolation

Enteric precautions are designed to prevent infections that are transmitted by direct or indirect contact with faeces.

Specification for Enteric Precautions

1. Private room is indicated if client's hygiene is poor. (A client with poor hygiene does not wash hands after touching infective material, contaminates the environment with infective material, shares contaminated articles with infective material, or shares contaminated articles with other clients.)

2. Masks are not indicated.

3. Gowns are indicated if soiling is likely.

4. Gloves are indicated for touching infective material.

Disease Requiring Enteric precautions

- Amoebic dysentery, Typhoid, Hepatitis A
- Cholera
- Coxsackievirus disease
- Enterocolitis caused by Clostridium difficile or Staphylococcus aureus
- Enteroviral infection

- Tetanus
- Gastroenteritis caused by
- *Campylobacter species*
- *Cryptosporidium species*
- *Dientamoebafragilis*
- *Escherichia coli* (enterotoxic, enteropathogenic, or enteroinvasive)
- *Giardia lamblia*
- *Salmonella species.*
- *Shigella species*
- *Vibrio parahaemolyticus*
- Viruses – including Norwalk agent and rotavirus

Protocol for receiving patient with Dengue and Chikungunya, Leptospirosis, Malaria

1. Receive the patient in isolation room. / ward.

2. Inform Infection Control Nurse.

3. Confirm report from laboratory.

4. Provide isolation measures with facilities of mosquito net, mosquito repellant.

5. Send notification card to Infection Control Nurse.

6. Infection Control Nurse will inform to DMHO – Health by telephone and then send notification through e-mail to DMO.

7. Instruct the relatives to protect themselves and others by keeping the environment free from mosquito.

Drainage / Secretion Precautions

Body substance isolation

Drainage /secretion precautions are designed to prevent infections that are transmitted by direct or indirect contact with purulent material or drainage from an infected body site.

Specification for Drainage /Secretion Precautions

1. Masks are not indicated.

2. Gowns are indicated if soiling is likely.

3. Gloves are indicated for touching infective material.

Disease Requiring Drainage / Secretion Precautions

The following infections are examples of those included in this category provided they are not

1. Caused by multiple resistant microorganisms;

2. Major draining (not covered by a dressing or does not adequately contain the drainage) skin wound, or burn infections, including those caused by Staphylococcus aureus or group A streptococcus.

3. Gonococcal eye infections in newborns. See contact isolation if the infection is one of these:

- Tetanus
- Abscess, minor limited.
- Burn infection, minor limited.
- Conjunctivitis.
- Decubitus ulcer, infected, minor or limited.
- Skin infection, minor or limited.
- Wound infection, minor or limited.

Blood body fluid isolation

This type is designed to protect the caregiver from getting infected by the disease.

1. Specifications for Blood and body fluid isolation:

a. Private room required only if the person's hygiene is poor.

b. Use of mask is indicated if the client is suffering from other infections e.g. Active Tuberculosis, Pneumonia etc.

c. Gowns are indicated if spoilage with blood and body fluids is likely.

d. Gloves are indicated for touching blood and body fluids.

e. Wash hands immediately if potentially contaminated by blood or body fluids.

2. Disease conditions requiring blood and body fluid isolation.

a. Acquired Immune Deficiency Syndrome.

b. Creutzfeld- Jacob Disease.

c. Hepatitis B (And HBsAg carrier).

d. Hepatitis C

e. Hepatitis non-A, non-B.

The following points are common for all the types of isolation.

a. Hands must be washed after touching the client or potentially contaminated articles and before taking care of any other client.

b. Stick BIO-HAZARD symbol on the contaminated articles before sending to the CSSD.

c. Discard all infectious wastes- non-plastic in yellow plastic bag.

MRSA Protocol:

1. Admission to an Isolation room

2. Single use Disposable plastic apron should be worn for patient contact

3. The gown/plastic apron & gloves should be removed before leaving the room

4. Single use disposable gloves should be worn for handling contaminated tissue, dressing or linen.

5. Hands must be decontaminated after removing the gloves

6. High efficiency filter type masks should be used for procedures that may generate aerosols

7. Bed linen / clothing should be changed daily

8. Linen bags must be sealed at the bed side and removed directly to the dirty utility area or the collection point

9. All instruments used for the patient care must be kept with the patient

10. Use dedicated equipments

11. Hand must be washed before and after contact with the patient or their environment .Use Chlorhexidine or alcoholic based hand rub.

12. All single use items must be disposed of as clinical waste. Clinical waste bags must be sealed before leaving the room. All reusable items would be processed in accordance with the local disinfection policy.

Visitor's Policy When Patient is in Isolation:

- The ward sisters and doctors concerned have the responsibility of informing the patients' relatives of the measures to be taken and the importance of restriction of visitors.
- The patient and the relatives must be given health education about the cause, spread, and prevention of the infection in detail. The need for isolation and restriction of visitors should be discussed with them.
- Hand washing after all contact with the patient has to be stressed.
- Visitors need to wear an N95 respirator. Be aware of restrictions on visitation due to outbreak or other conditions within the facility.
- No more than two adult visitors should be allowed at a time during the hospital visiting hours and the length of stay should be governed by the needs of the patient.
- Children below 12 years of age should not be allowed into isolation areas.

• Visitors' footwear, bags, and other belongings should be left outside the room.

• Visitors should not be allowed to sit on the patient's bed.

• Visitors should wash their hands well with soap and water before entering and when leaving the room.

• Any prophylactic medication or active immunization for attendants should be conducted by the physician in charge

Policy on pre and post exposure prophylaxis including spill management

Purpose:

- To support the immediate assessment, management and follow-up of individuals who have been exposed (or suspect they have been exposed) to blood borne viruses (BBV), and recommendations for initiation of post-exposure prophylaxis (PEP) in occupational settings.

Scope:

- Documentation of events related to post exposure prophylaxis (accidental exposure record form)
- Training on standard precautions and pre & post exposure prophylaxis
- Training on blood and body fluid spill management
- To develop an action plan and function accordingly.

NEEDLE STICK INJURY PREVENTION AND MANAGEMENT

INTRODUCTION:

An occupational exposure is defined as:

- A percutaneous injury (e.g. Needle stick or cut with a sharp instrument);
- Contact with the mucous membrane of the eye or mouth;
- Contact with non-intact skin (particularly when the exposed skin is chapped, abraded, or afflicted with dermatitis);
- Or contact with the intact skin when the contact duration is prolonged (e.g., several minutes or more) with blood or other potentially infectious body fluids.

Agents transmitted:

- Hepatitis B- risk of transmission following occupational exposure is 5-30%.
- Hepatitis C- risk of transmission following occupational exposure is 3-10%.

- HIV-risk of transmission following occupational exposure is 0.3% (percutaneous) and 0.09% (mucosal splash).

Infection specimen for needle stick, sharp and splash injury:

- *Potentially infectious body fluids* include blood, semen, vaginal secretions, CSF, synovial fluid, pleural fluid, amniotic fluid or other body fluids contaminated with visible blood.
- *The following are not considered potentially infectious,* unless visibly contaminated with blood: Faeces, nasal secretions, saliva, sputum, sweat, tears, urine and vomitus.

Factors that influence Risk of contracting infection following occupational exposure:

The risk of infection, following exposure, varies with the type of exposure:

- Type of needle (hollow bore vs. solid)
- Device visibly contaminated with patient's blood
- Depth of injury
- The amount of blood involved in the exposure
- The amount of virus (viral load) in the exposed blood/body fluid at the time of exposure
- Timely performing first aid
- Timely (<2hours and up to 72 hours) start of correct PEP.

PREVENTION OF OCCUPATIONAL EXPOSURE

General infection control measures to protect against blood-borne viruses

- Apply standard infection control precautions.
- **3 All:** All patients, all blood/body fluid and all sharps should be considered infectious unless proved to be negative.
- ***Use appropriate PPEs:*** Wear gloves, gowns/aprons, masks, and goggles , while handling all potentially infectious material.
- ***Adhere to hand hygiene:*** Thoroughly wash hands with water and soap after removing gloves, handling infectious materials, before leaving the laboratory area, and immediately after any contamination of skin surfaces.
- ***Avoid wearing*** open footwear in situations where blood may be split, or where sharp instruments or needles are handled.
- For all clinical procedures, *cover existing wounds, skin lesions, and all breaks* in exposed skin with water proof dressings or with gloves if hands extensively affected.
- ***Work precaution:*** HCWs with *chronic skin disease* (e.g. eczema) should avoid invasive procedures, which involve sharp instruments or needles when their skin lesions are active, or if there are extensive breaks in the skin surface.

- ***Work surfaces infected:*** with 0.1 percent sodium hypochlorite solution.
- ***All must be immunized against HBV*** (Refer hepatitis vaccination)
- ***Clear up spillage*** of blood and other body fluids promptly and disinfect surfaces.

Precautions while handling sharp objects (like needles, lancets, scalpels, etc.):

- Avoid unnecessary use of sharps and needles. Use of alternative instruments, cutting diathermy, and laser.
- Disposable needles should be used.
- Handle hollow bore needles with care as it may lead to deep injuries.
- Never recap needles- If unavoidable, use single hand –scoop technique.
- Never break/ bend needles by hand.
- Needles/sharps should not be left on trolleys and bedside tables and must be disposed of immediately.
- Never pass used sharps from one person to another directly.

Dispose sharps in a puncture resistant container containing 10% sodium hypochlorite solution.

Prevention of sharp injury during surgical procedures

- *Confine and contain* approach should be implemented for every procedure.
- *Preoperative testing* of a patient for Blood borne viruses (BBVs)should be basis of clinical condition.
- *Surgery list* should be scheduled on the basis of clinical urgency, and in such a way as to allow ample time for adequate infection control procedures to take place
- In addition to the standard infection control precautions, the patient known to have BBV infections may require the following additional precautions for surgical operation:
    - The lead surgeon should ensure that all members of the team know of the infection hazard and appropriate measures should be followed such as use of double gloves.
    - The surgical team must be limited to essential members of trained staff only.
- *Hair removal:* Depilatory creams should be used for essential hair removal.
  Unnecessary equipment should be removed from theatre.

  Special surgical equipment reserved for these patients is not essential.

    - ***Passing of sharp instruments***
    - Before any surgical procedure, the surgeon and scrub nurse should decide on the route for passage of sharp instruments during the procedure.
    - This may entail the designation of a ‘neutral zone’.

- The surgeon must avoid placing his/her less dexterous hand in potential danger.
- *Non-touch approach*- Sharp instruments *should not be* passed by hand.
- Only one sharp at a time should be passed.
- A specified *puncture-resistant sharps tray* must be used for the transfer of all sharp
- If two surgeons are operating- then each surgeon needs his/ her own sharp trays.

- **Diathermy and suction devices** should be placed on the opposite side of the table to the surgeon, thereby ensuring the assistant dose not reach across the table between the surgeon and nurse.
- **Variations in operative technique** may be adopted such as cutting (e.g, with lasers), or of wound closure that obviate the use of sharp instruments and lessen the risk of inoculation.
- **Suturing**
    - Needles must never be picked up with the ffingers while suturing. Forceps or a needle holder is ideal for holding needle.
    - Where practical, blunt needles should be used to close the abdomen.
    - Where practical, suture needles should be cut off before knots are tied to prevent NSI.
    - Surgeons may use a sterile thimble on the index finger of the less dexterous hand for protection when suturing.
    - Wire sutures should be avoided where possible because of the high risk of NSI.
    - After a surgical procedure, the skin should be used closed with staples whenever possible.
    - Hand-held straight needles should not be used, curved needle is ideal.

- **Retraction**
    - Hands of assistant HCWs must not be used to retract the wound on viscera during surgery.
    - *Self- retaining retractors* should be used, or a swab on a stick, instead of fingers.
    - Certain instruments should be avoided unless essential to procedure, for example, sharp wound retractors such as rake retractors and skin hooks.
- **Drainage and dressing**
    - Closed wound drainage systems should be used, where appropriate.
    - Wound dressings with impervious outer covering to contain wound exudates should be used.
    - Blood should be cleaned off the patient's skin as far as possible at the end of operation.
- **Disinfection of surgical items after procedure**
    - Disposable items should be used wherever possible

- Reusable items must be decontaminated by the CSSD as per hospital CSSD policy.

- **Cleaning of operation theater and waste disposal:**
  - Adequate time must be provided at the end of each case to allow for thorough cleaning
  - Cleaning of the operating theater and the appropriate disposal of clinical waste should be carried out as per hospital policy
  - Used linen and theater clothing should be handled in accordance with local policy

Prevention of splash injury

- Appropriate use of PPE during surgeries, during labour (amniotic fluid exposure)
- Certain high risk surgeries (cardiac surgeries) with anticipated risk of damaging great vessels require complete set if PPE s including face shield and goggles.
- Laboratory personnel should refrain from mouth pipetting, eating, drinking, or smoking in the work area.
- Spillage management should be done as per hospital policy (10% hypochlorite)

Engineering controls to prevent NSI:

Various engineering controls have been tried to prevent NSI, with mixed results in the studies. Few of them are being described below:

- Replacement of the hollow bore needles for injection and blood drawing
  - Becton Dickinson 3 milllimeter (ml) Safety- Lok syringe with a 23 gauge needle and a protective sheath
  - Puncture Guard bluntable vacuum tube blood collection needle (Bio plexusInc.)
  - Venipuncture Needle Pro resheathable vacuum tube blood collection needle (Protex Inc.) for phlebotomy.
  - Recapping blocks, single use evacuated tube holders, retractable and lancets and retractable capillary puncture devices
- Needleless IV systems include
- Blunt suture needles
- Study was done by testing the used gloves of surgeons for perforation
- Safety engineered IV systems
- Retractable lancets
- Assistive devices

- Recapping guard – a plastic shield with central hole that receives the capped end of the needle- helps to remove and replace the cap or sheath of the needle while keeping the non-active hand protected
- Disposal Boxes
  - Change the location to patient bedsides
  - Change in box design to open top or letterbox or units with higed lids.
  - Use of rigid disposal container
- Use of double gloves

MANAGEMENT FOLLOWING OCCUPATIONAL EXPOSURE

Dos and Don'ts for the Exposed Individual

Don'ts	Do's
• Do not panic • Donot place the pricked finger into the mouth reflexively • Do not squeeze blood from wound • Do not use bleach, alcohol , iodine, antiseptic , detergent,etc.	• Stay calm • Remove gloves,if appropriate • Wash exposed site thoroughly with running water and soap. Irrigate thoroughly with water, if splashes have gone into the eyes or mouth • Consult the designated physician/personnel immediately as per institution guidelines, for management of the occupational exposure

Steps of Post Exposure Management

Steps to be followed after accidental exposure to blood/other potentially infectious materials:

1. First aid
2. Check online report of source status if available
3. Take first dose of PEP for HIV
4. Report to designated centre for NSI management
5. Testing for HIV, HBV and HCV for source and status
6. Risk assessment (based on type of injury and source status
7. Decision on prophylactic treatment for HIV and HBV
8. Monitoring and follow up of HIV, HBV and HCV status.

9. Documentation and recording of exposure.

1. First aid: Management of Exposed site

For skin:	*For the eye:*	*For mouth:*
• Immediately wash the wound and surrounding with water and soap, and rinse. • Do not scrub • Do not use antiseptics or skin washes	• Immediately irrigate the exposed eye thoroughly with running tap water or normal saline at least for 5 min for blood splash (15 min for chemical splash) • If wearing contact lenses, leave them in place while irritating. • Once eye is cleaned, remove the contact lens and clean them in a normal manner. • Do not use soap or disinfectant on the eye.	• Spit fluid out immediately • Rinse the mouth thoroughly using water or saline and spit again. Repeat the process several times. • Do not use soap or disinfectant in the mouth.

2. Check online report of source status if available

- If source is found to be negative, do not take first dose of PEP and directly documenting the NSI.

3. Take first dose of PEP for HIV

If the source status is unavailable at online report, or found as positive for HIV or source is unknown, then go to the PEP nodal centre of the hospital to take first dose of PEP.

4. Report to designated centre for NSI management.

Every hospital must possess a designated centre for NSI reporting and management. They should provide 24 hours help line support.

5. Testing for HIV, HBV and HCV for source and HCW

- Once the HCW reports to the nodal centre, both the source and the HCW are tested for their baseline status for HIV (antibody), HCV (antibody), and HBV (HBs Ag).
- If HCW is prior vaccinated, then check for HBsAb titre.
  (HCW's baseline status is determined. Otherwise, it may be difficult to attribute the infection acquired due to exposure in the occupational setting. This may have bearing on the claims for compensation from the health authorities.)

6. **Decision on prophylactic treatment for HIV and HBV:** This is based on assessment of exposure and source status.
   - Prophylactic treatment for HBV –Described later in this chapter.
   - Prophylactic treatment for HIV – PEP is continued for 28 days in all sources positive and source unidentified cases, regardless of the risk of exposure and CD4 count of the source.
   - PEP for HIV: to use

PEP for HIV: NACO 2015 GUIDELINE RECOMMENDATION

• PEP is continued for 28 days in all source positive and source unidentified cases, regardless of the risk of exposure and CD4 count of the source.
• Single tablet of TLE (Tenofovir 300 mg plus Lamivudine 300 mg plus Efavirenz 600mg) once daily for 4 weeks.
• The first dose should be started within 2 hours and definitely within 72 hours of exposure.
• Regimen for primary management of the exposure in pregnant women is essentially same as that of non-pregnant persons.
• Exposed individuals who are known or discovered to be HIV positive should not receive PEP. They should be thoroughly counseled and should be assessed for continuation of HAART.
• **Side effects and Adherence to PEP:**
• Common side effects during PEP medication are-
  o At the beginning –nausea, diarrhoea, muscular pain , headache and fatigue
  o Later during the course-Aneamia, leukopenia, thrombocytopenia

- Counsel the patient to continue the PEP and to take medication to reduce the side effects.
- >95% adherence is important to maximize the efficacy of PEP
- A complete blood count and liver function test (transaminases) may be performed at the beginning of treatment (as baseline) and after 4 weeks.

7. Monitoring and follow up of HIV , HBV and HCV status

- The person should be provided with pre-test counseling and PEP should be started as discussed below.
- HIV testing follow-up is done: at 6 weeks, 3 months and 6 months after exposure.
- HBV and HCV testing follow-up is done: at 3 months and 6 months after exposure.

8. **Precautions during the follow-up period-**During the follow up period, especially the first 6-12 weeks, the following measures are to be adopted by the HCW.
    - Refraining from blood, semen, organ donation
    - Abstinence from sexual intercourse or use of latex condom
    - Women should not breast feed their infants.
    - The exposed person is advised to seek medical evaluation for any febrile illness that occurs within 12 weeks of exposure.
9. **Informed consent and counseling:** Almost every person feels anxious after exposure. They should be counseled and psychological support provided.
        - They should be informed about the risks and benefits of PEP medications.
        - It should be clear that PEP is not mandatory.
        - Exposed persons should, however, be made to understand that a few cases of transmission have been seen in cases given prophylaxis.
10. **Documentation and recording of exposure:**
    - ***A structured proforma*** (figure-2) should be used to collect the information related to exposure: Date, time, and place of exposure, type of procedure done, type of

exposure: percutaneous, mucus membrane, etc., duration of exposure and exposure source and volume; type of specimen involved.

- ***Consent form-*** For prophylactic treatment, the exposed person must sign a consent form. If the individual refuse to initiate the PEP, it should be documented. The designated officer for PEP should keep this document.

HEPATITIS B POST EXPOSURE PROPHYLAXIS FOR HEALTHCARE WORKERS:

1. **If the source is unknown how should it be managed**When the source person is unknown the exposed HCW should be managed as if source person is positive.
2. **If the exposure is from a needle lying randomly should they be assessed-** Testing needles or other sharp instruments implicated in an exposure is not recommended. Institutions should ensure that HCW have timely access to post exposure management and prophylaxis.
3. **Managing HCW with from a needle stick, sharp or blood splash exposure:**
    - **For vaccinated HCW with subsequent documented anti-HBs>10 mIU/ml-**No need to assess the source status. No post exposure management is necessary.
    - ***For vaccinated HCW with anti HBs<10mIU/ml after two complete vaccination series (i.e. non-responders)-***
      Assess the source status as soon as possible. If the source status is positive or unknown give 2 doses of HBIg, one month apart.

For vaccinated HCW whose antibody titres are unknown- Check the titres and assess the source risk as early as possible.

- If the titres are >10 mIU/ml, no action needed irrespective of the source status
- If the titres are >10 mIU/ml and if the source is negative, give revaccination series of hepatitis B (0-1-6).
- If the titres are <10 mIU/ml and if the source is positive or unknown give one dose of HBIg and start revaccination series of hepatitis B.

If the HCW is unvaccinated or incompletely vaccinated or vaccine refusers and if the source is positive or unknown-

Do HbsAg and anti HBc for the HCWs and give HBIg one dose and complete the vaccination series. If the source is negative, complete the vaccination schedule.

4. **When to check HBsAb titre**
    - Done after 1-2 months of the last dose of hepatitis B vaccine.
    - When immunoglobulin is received along with vaccination, post vaccination serology is done after 4-6 months to avoid detection of **passively administered anti-HBs.**

NEEDLE STICK INJURY
(Post exposure prophylaxis)

DO NOT SQUEEZE

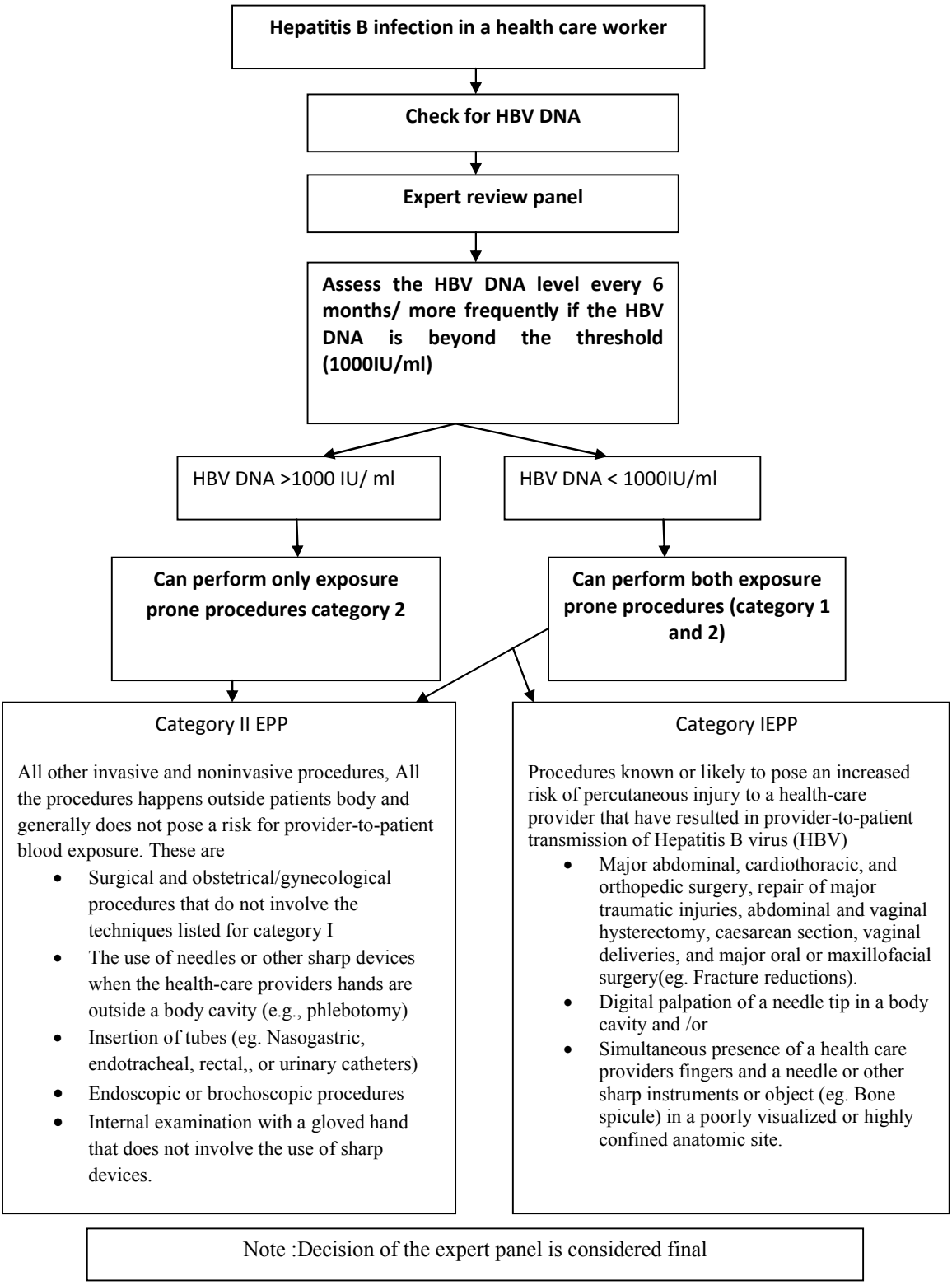
1. Wash hand in running water with soap

2. Inform Infection Control Nurse.

3. If housekeeping staff injured,

a. Inform housekeeping supervisor and Housekeeping Supervisor is responsible to inform infection control nurse.

Guidelines for exposure prone procedures for HCWs carriers for Hepatitis B



Procedure to be followed for sharp injury to health care worker

Needle stick Injury

↓

First Aid

The affected area must be washed thoroughly with running water

Practice of milking out or more blood is more controversial and is not recommended by CDC

↓

Report to supervisor /Sister in-charge

↓

Record in occupational Exposure Register

↓

Seek Immediate Medical consultation

↓

Blood testing should be done immediately. Results must be produced within 45 minutes.

As treatment for HIV must be initiated within 1-2 hours.

↓

Track patient blood results	
HIV antibody **HBs Ag** **Anti-HCV antibody**	**Victim-HCW**
	HIV antibody **HBs Ag** **Anti-HBs antibody** **Anti-HCV antibody**

↓ ↓

Recommendations for health care worker in suspected cases of HIV, HBV and HCV

Recommendations for health care worker in suspected cases of HIV, HBV and HCV

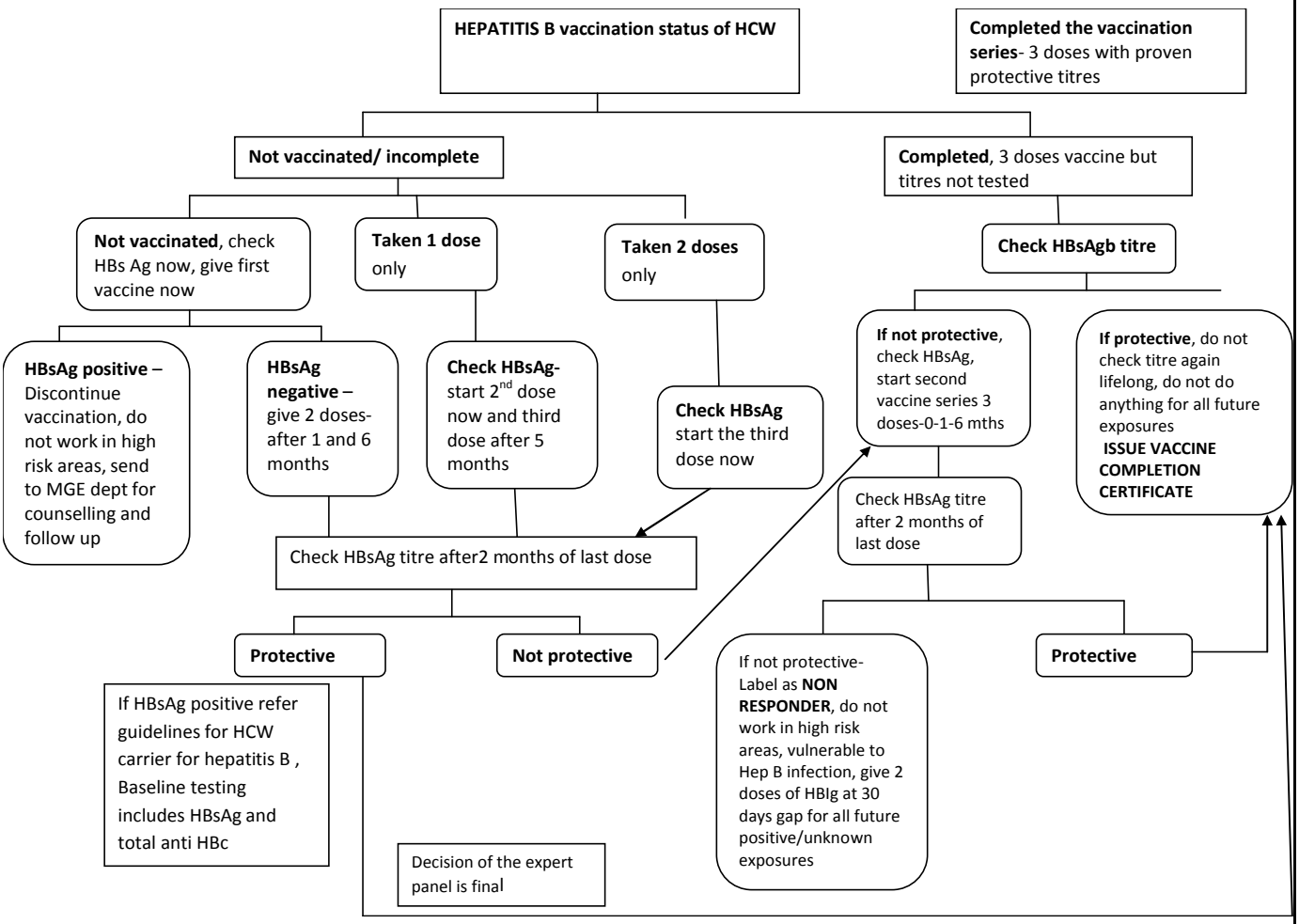
Serological status of Index case	Status of index case	Recommendations for health care worker	Follow up of the health care worker
HIV	If positive	Counseling Initiate HAART therapy within 1-2 hours and continue for 28 days HAART regimen is a combination of ATV/r + TDF/FTC or RAL+TDF/FTC or LPV/r (once or twice daily)+ TDF/FTC or EFV+ABC/3TC (only for patients who are HLA-B*5701 negative	Check HIV antibody levels at 6 weeks, 3months and 6 months
	If Negative	Counseling No prophylaxis needed	Check HIV antibody levels at 6 weeks, 3months and 6 months
HBV	If positive	Counseling Give HBIG prophylaxis (0.6mIU/ml intramuscularly) within 24 hours Anti-HBs antibody levels >100mIU/ml-No vaccination needed 10-100mIu/ml- Booster only <10mIU/ml-Full Vaccination +HBIG	Follow up is not required
	If Negative	Counseling No prophylaxis needed	Follow up is not required
HCV	If positive	No prophylaxis available Early Identification of the disease by regular follow- up Treatment if disease occurs	Check anti-HCV antibody levels at 3 months and 6 months

Infection control nurse to monitor, follow up and maintain documents.

Vaccination of Health care workers:

Vaccines recommended for Health care workers:

Vaccine	Dose and Remarks
Hepatitis B	Three-dose series at 0, 1and 6months Test for Hepatitis B surface antibody (anti HBs) to document immunity 1-2 months after third dose If anti HBs is atleast 10 mIU/ml, patient is immune No further serologic testing or vaccination recommended If anti HBs is less than 10 mIU/ml (negative), patient is unprotected from Hepatitis B virus (HBV) infection; revaccinate with three-dose series. Retest Anti HBs ,1-2 months after dose-3 If AntiHBS is negative after 6doses of vaccine, patient is a nonresponder
Measles, Mumps, Rubella (MMR)	Two doses four weeks apart
Tetanus	Booster once every ten years
Meningococcal vaccine	One dose to HCW who might contact patients with meningococcal infections
Varicella	For HCW who have no serologic proof of immunity, prior vaccination or history of Varicella disease **(Chicken Pox)** Two doses of Varicella vaccine, four weeks apart
Influenza	Appropriate dose of vaccine which confers protection from the current circulating epidemic strain must be given, as and when available, and recommendations by Government of India must be followed


HEPATITIS B vaccination status of HCW
Completed the vaccination series- 3 doses with proven protective titres
Not vaccinated/ incomplete
Completed, 3 doses vaccine but titres not tested
Not vaccinated, check HBs Ag now, give first vaccine now
Taken 1 dose only
Taken 2 doses only
Check HBsAgb titre
HBsAg positive – Discontinue vaccination, do not work in high risk areas, send to MGE dept for counselling and follow up
HBsAg negative – give 2 doses- after 1 and 6 months
Check HBsAg- start 2nd dose now and third dose after 5 months
Check HBsAg start the third dose now
If not protective, check HBsAg, start second vaccine series 3 doses-0-1-6 mths
If protective, do not check titre again lifelong, do not do anything for all future exposures
ISSUE VACCINE COMPLETION CERTIFICATE
Check HBsAg titre after2 months of last dose
Check HBsAg titre after 2 months of last dose
Protective
Not protective
If not protective- Label as NON RESPONDER, do not work in high risk areas, vulnerable to Hep B infection, give 2 doses of HBIg at 30 days gap for all future positive/unknown exposures
Protective
If HBsAg positive refer guidelines for HCW carrier for hepatitis B , Baseline testing includes HBsAg and total anti HBc
Decision of the expert panel is final

NEEDLE STICK INJURY MANAGEMENT IN SVIMS

4STEPS TO BE FOLLOWED AFTER EXPOSURE (Blood/ Body fluid/ Mucocutaneous exposure)

1. **FIRST AID- CLEAN THE SITE**
   Needle Stick Injury- Wash with soap and water

   Don't squeeze the area

   Don't put into mouth

   Mucocutaneous – Wash with Clean water.

2. **CONTACT TO THE NODAL CENTER IMMEDIATELY**
   EMD- 2259

   MICU-2257

3. **TAKE THE FIRST DOSE OF PEP** at the nodal centre within two hours irrespective of the HIV status of the source
4. **FOR FURTHER FOLLOW UP& ENQUIRY-**
   HOSPITAL INFECTION CONTROL COMMITTEE (HICC)

   2ND Floor, Microbiology Lab, OPD Block

   Help Line Numbers:

   Intercom-2254

   Landline (HICN) - 0877 2287777 extension 2243

   Mobile (Emergency): 94923665555

   Prepared by HICC Verified by SQC Approved by Director cum VC

Figure – Needle stick injury awareness poster, SVIMS

Reference:

1. National AIDS Control Organization (2015). National AIDS Control Organization-Annual Report.Department of AIDS Control Society, Ministry of Health and Family Welfare.

2. CDC-Bloodborne Infectious Diseases-EmergencyNeedle stick Information-NIOSH Work place Safety and Health Topic (Internet).(cited 2016 Dec 5).Avialable from: http://www.cdc.gov/niosh/topics /bbp/emergnedl.html

3. Schillie, TV Murphy, M Sawyer, K Ly, E Hughes et al. MMWR Recommendation 2013-cdc.gov CDC guideline for evaluating health-care personnel for hepatitis B virus protection and for administering post exposure management.

PRINCIPLES OF SPILLS MANAGEMENT

- Blood and body fluid spillages should be dealt with immediately or as soon as it is safe to do so.
- Other persons should be kept away from the spillage until the area has been cleaned and dried.
- Care should be taken if there are sharps present and should first be disposed of approximately into a sharps container.
- Spills should be removed before the area is cleaned.
- Area should be well ventilated if using chlorinating agents.
- Adding liquids to spills increases the size of the spill and should be avoided.
- Chlorinating agents should be used (10% hypochlorite) in a well ventilated area and are generally only recommended on a small spill.
- Chlorinating agents should not be placed directly on spillages of urine.
- Chlorinating agents are not suitable for use on soft furnishings.
- It is recommended that supplies of personal protective equipment, paper towels and healthcare risk/yellow waste bags are available for spills management.
- If non-disposable cloths/mops are used to clean spillage are they must be thermally or chemically disinfected.
  Spill Kit.

  A Spill kit should be readily available in each clinical care should include the following.

Scoop and scraper	Absorbent agent	Rough cloth

Single-use gloves	Clinical waste bags and ties	Bleach
Protective aprons	Disposable forceps	Two cardboard pieces
Surgical mask and eye protection	Detergent	Instruction chart

All parts should be disposable to ensure that cross-contamination does not occur.

Protocol for management of body fluid splash & spillages

Blood and body fluid spillage

- Prepare 1% hypochlorite solution (200 ml 5% hypochlorite in 800 ml of water)
- Wear gloves pour 1% hypochlorite on the spillage
- Cover it with a piece of paper or cloth
- Keep it there for 10 – 20 minutes
- Wipe the spillage using the covered paper or cloth
- After wiping discard the same in the yellow cover
- If it is a large spillage, after covering the spillage with paper or cloth
- Mop it with Separate mop (mop should be dipped in 1 % hypochlorite for 30 minutes)

Spot Cleaning:

- Select appropriate PPE
- Wipe up spot immediately with damp cloth, tissue or paper towel
- Discard contaminated materials
- Perform hand hygiene

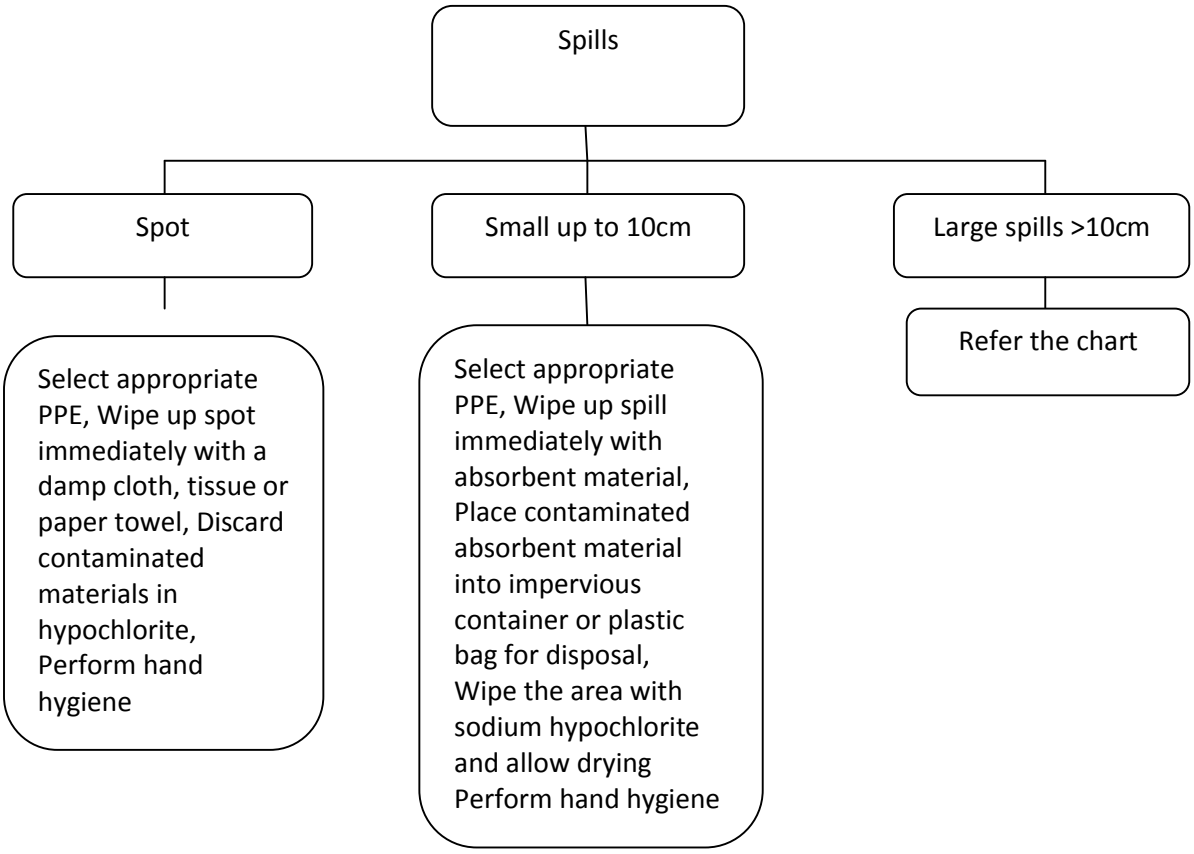
Small spills (up to 10 cm diameter):

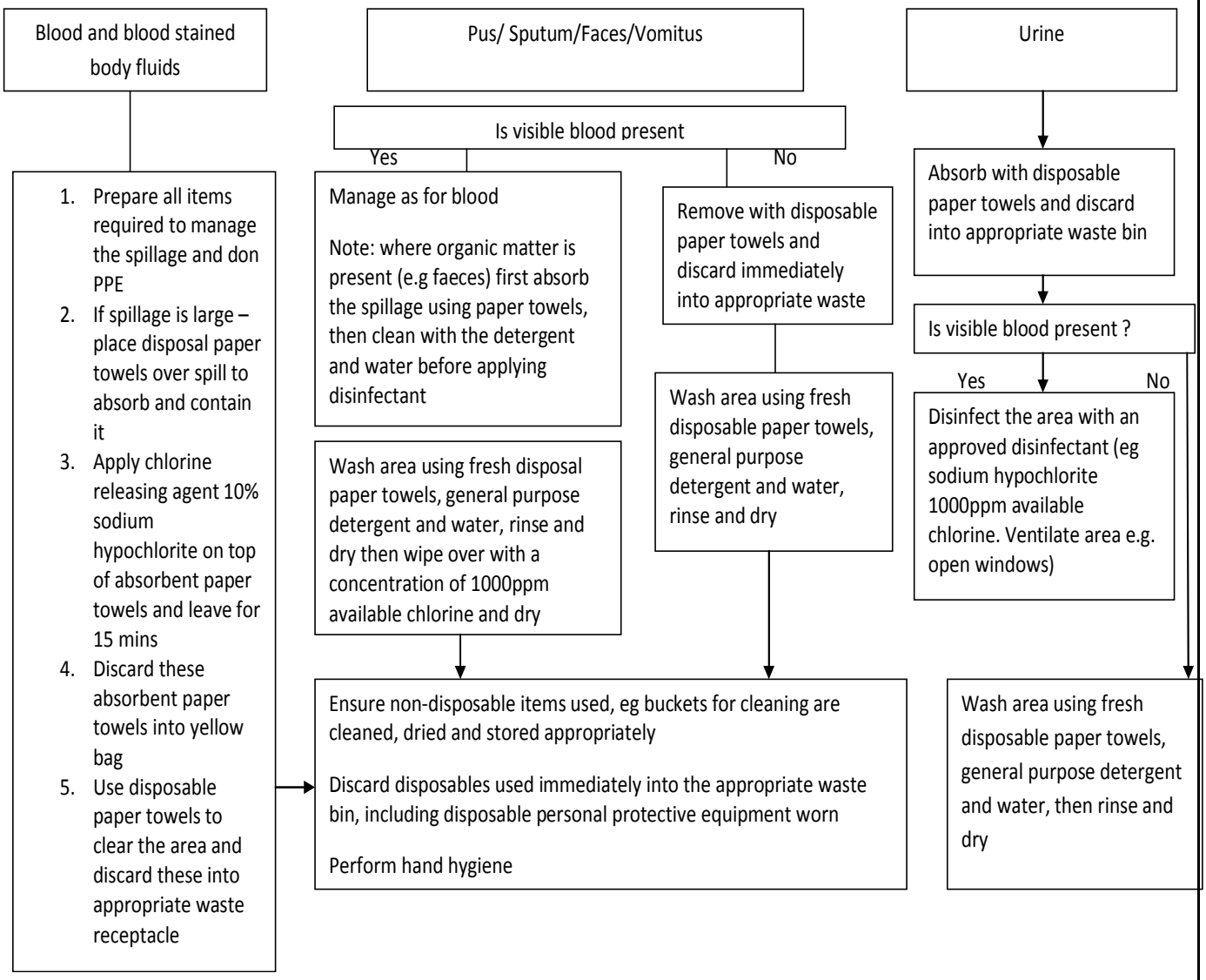
- Select appropriate PPE
- Wipe up spill immediately with absorbent material
- Place contaminated absorbent material into impervious container or plastic bag for disposal
- Clean the area with warm detergent solution, using disposable cloth or sponge
- Wipe the area with sodium hypochlorite and allow to dry
- Perform hand hygiene

Large spills (greater than 10 cm diameter)

- Select appropriate PPE
- Cover the area of spill with an absorbent clumping agent and allow to absorb

- Use disposable scraper & pan to scoop up absorbent material and any unabsorbed blood or body substances
- Place contaminated material into impervious container or plastic bag for disposal
- Discard contaminated material
- Mop the area with detergent solution Wipe the area with sodium hypochlorite and allow to dry
- Perform hand hygiene




Blood and blood stained body fluids
Pus/ Sputum/Faces/Vomitus
Urine
Is visible blood present
Yes
No
1. Prepare all items required to manage the spillage and don PPE
2. If spillage is large – place disposal paper towels over spill to absorb and contain it
3. Apply chlorine releasing agent 10% sodium hypochlorite on top of absorbent paper towels and leave for 15 mins
4. Discard these absorbent paper towels into yellow bag
5. Use disposable paper towels to clear the area and discard these into appropriate waste receptacle
Manage as for blood
Note: where organic matter is present (e.g faeces) first absorb the spillage using paper towels, then clean with the detergent and water before applying disinfectant
Wash area using fresh disposal paper towels, general purpose detergent and water, rinse and dry then wipe over with a concentration of 1000ppm available chlorine and dry
Remove with disposable paper towels and discard immediately into appropriate waste
Wash area using fresh disposable paper towels, general purpose detergent and water, rinse and dry
Absorb with disposable paper towels and discard into appropriate waste bin
Is visible blood present ?
Yes
No
Disinfect the area with an approved disinfectant (eg sodium hypochlorite 1000ppm available chlorine. Ventilate area e.g. open windows)
Ensure non-disposable items used, eg buckets for cleaning are cleaned, dried and stored appropriately
Discard disposables used immediately into the appropriate waste bin, including disposable personal protective equipment worn
Perform hand hygiene
Wash area using fresh disposable paper towels, general purpose detergent and water, then rinse and dry

Policy on outbreak management

Purpose:

- To ensure that the organisation is able to initiate prompt recognition of an outbreak of a healthcare associated infection or a communicable disease, to control further spread, prevent recurrence and to maintain satisfactory communication with other agencies having a legitimate interest in the outbreak.

Scope:

- The statements included in the policy apply to all in-patient areas across the organization.
- To report suspected outbreaks immediately to the Hospital Infection Control Team.
- To ensure that procedures for the implementation of the Outbreak Policy is continually reviewed and improved as required within the organization.

SVIMS HOSPITAL documents the procedures for identifying and managing an outbreak*.

OUTBREAK MANAGEMENT

INTRODUCTION AND DEFINITION

An outbreak of infection or food borne illness may be defined as

- Two or more linked cases of the same illness or
- The situation where the observed number of cases exceeds the expected number, or a
- Single case of disease caused by a significant pathogen(e.g. diphtheria or viral hemorrhagic fever) or
- Occurrence of disease at a rate greater than that expected within a specific geographical area and over a period of time

a. Detecting an Outbreak*:

Warning signs of an impending outbreak:

- Clustering of cases or deaths in time and/or space
- Unusual increase in number of cases or deaths
- Even a single case of measles, AFP, Cholera, Plague, dengue or JE
- Acute febrile illness of unknown aetiology
- Occurrence of two or more epidemiologically linked cases of meningitis, measles
- Unusual isolate
- Shifting in age distribution of cases
- Sudden increase / high vector density

- Natural disasters

Table: Classification of outbreaks

Outbreaks may be classified in two ways	
1.confined to some of the members of one family or 2. widespread-involve cases either locally, nationally, or internationally.	A. obvious, such as in an episode of food poisoning that affects both HCWs and patients B.insidious-reach considerable proportions before they become apparent. These outbreaks are detected by the laboratory

Case definitions

Table: Case definition in an outbreak situation can be divided into three categories:

1)Confirmed case:	**2)Probable case:**	**3)Possible case:**
• The patients have clinical signs and symptoms of the disease and • The diagnosis is confirmed by laboratory analysis of the appropriate specimen(s)	• The patients have clinical signs and symptoms of the disease or • The patients epidemiologically linked(been exposed to a confirmed case, eaten the same food, stayed in the same hotel, etc.) to a confirmed case	• The patients have clinical signs and symptoms without being a confirmed or probable case.

The epidemic curve

An epidemic curve is a graph is a graph (histogram) in which the cases of a disease that occurred during an outbreak/epidemic are plotted by date of onset of illness and this information is gathered from line listing of all the cases during an outbreak. This curve depicts the number of cases/patients on the vertical (y) axis, and time on the horizontal (x) axis.

The shape of the curve can provide data on the mode of transmission and help us to:

- Determine whether the source of infection was common or continuous or both.
- Identify the probable time of exposure of the cases to the source(s) of infection.
- Identify the probable incubation period.
- Determine if the problem is ongoing or not.

Table: point source versus continuous source

Point source	Continuous source
• All cases have the same origin, i.e. index case/case person or a single vehicle will be primary reservoir or means of transmission. • E.g. if there is an abrupt increase in the number of cases over a short period, the curve suggests single exposure to a point source of contamination. • Epidemic curve approximates a normal distribution curve if: o Who has been either not noticed or o Not reported initially or o Has been discharged from hospital	• The infections are transmitted from a reservoir • Cases occur over a longer period • Epidemics can occur due to o Person to person transmission, o From the environment, or o From contaminated food or water. • To determine the probable period of exposure of cases in a continuous source outbreak it is necessary to know the- o Specif8ic disease involved, o Dates of onset of cases, and o Either mean or median, or minimum and maximum, incubation period(s) for the specific disease. • It is important to note that exposure may be o Continuous continuous o Intermittent continuous; curve curve will have irregularly spaced peaks.

Response to an outbreak and control measures:

Sometimes trigger events indicate a potential outbreak. Details of these are given below.

Preset trigger levels for diseases will be identified with specific responses identified for various levels. The levels will depend on the epidemic potential, case fatality of the disease and the prevalence of the problem in the community(s)

Trigger Level-1	Suspected /limited outbreak	Local response by health worker and MO(Medical officer)
Trigger Level-2	Outbreak	Local & District Response by ORT (Out break response team)
Trigger Level -3	Confirmed Outbreak	Local, District and State level response
Trigger Level-4	Wide spread Epidemic	State Level response to an epidemic
Trigger Level-5	Disaster Response	Local, District, State, Centre & Partners

- In a non-endemic area even 1 case of suspected epidemic prone disease should initiate a trigger response at various levels e.g. report of an AFP case in an areas which has not reported any polio case in last one year.
- In an endemic region change in pattern of disease or evidence of clustering of disease should be considered a trigger event e.g. report of more than 10 cases of jaundice from an urban ward in a week.

The First Information Report should be submitted to the Outbreak Response Team by the reporting unit as soon as verification of the suspected epidemic is made.

The fastest route of information available will be used. This may be by Telephone, Fax, E-mail.

Summary of Outbreak Preparedness

- Formation of the Outbreak Response Team
- Training for the Outbreak Response Team
- Regular review of the data
- Identifying ‘outbreak seasons’
- Identifying ‘outbreak regions’

- Ensuring that these regions have the necessary drugs and materials (including transport media) prior to the ‘outbreak season’
- Identifying and strengthening the appropriate labs
- Designating vehicles for outbreak investigation and ensuring that it is in working condition.
- Ensuring that communication channels like telephones are in working condition.

OUTBREAK CONTROL MEASURES

There should be a general out break control guideline in hospital which must be reviewed periodically and updated every one to two years and urgently if needed.

Role of treating clinical team

Whenever an outbreak is suspected, the clinical team should do the following immediately.

Table: Role of clinical team if outbreak is suspected

Inform	Isolate	Implement
• All suspected outbraeks should be reported to HICC and microbiology lab	• All the suspected cases should be isolated as soon as possible • Record information on all cases with date of admission, time of onset of symptoms, clinical diagnosis, etc. • Relevant specimens for investigation should be sent to the laboratory after consultation with the member of the HICC team and medical microbiologist. • Restrict movement of staff and patients.	• Appropriate infection control measures must be implemented • Based on the most likely mode of transmission of pathogens as per local infection control guidelines.

Role of HICC

The rapid recognition of outbreaks is one of the most important objectives of HICC.

Infection control practitioner must have good understanding of the microbiology and diagnostic methods used in diagnosis of infectious diseases. The HICC team must do the following:

- Gather all the relevant information by visiting the ward(s) of facility
- Line listing of all the essential clinical and laboratory information and
- Establish the local endemic rate.
- Pause and reflect and rethink: Is it really an outbreak? Or a pseudo outbreak?

Is it really an outbreak?

Pseudo-outbreaks are common and there may be several reasons:

- Laboratory factors: due to new test, new trained technicians, and contaminated or normal flora or colonization interpreted as pathogen

Environmental factors-contaminated tap water used in endoscope cleaning and performing ZN stain

Role of microbiology laboratory during outbreak

Microbiology lab should actively collaborate in epidemic investigations and collection of specimens.

- The diagnosis must be given as soon as possible by use of never rapid method
- Accurately identify the causative organisms to species level.
- Accurately determine the antimicrobial susceptibilities.
- Send the microorganisms to reference laboratories for appropriate typing to establish an epidemiological link.
- Store microorganisms and/or acute serum sample for further investigations.
- Carry out internal quality control on a regular basis and participate in the external quality control program.
- Before introduction of a new test or a method, it must access evidence both for sensitivity and specificity of the test and ensure its cost-effectiveness.

What next if outbreak is confirmed:

If the outbreak is confirmed, the HICC team will do the following-

- Immediate implementation of preliminary infection control measures
    - Reinforcement of standard precautions stressing on five moments of HH
    - Implementation of relevant transmission- based precautions, including isolation and cohorting which is usually based on mode of spread of microorganisms
- Discuss with appropriate personnel to constitute an outbreak control committee(OCC)

Outbreak control committee (OCC):

Most minor outbreaks in hospital are successfully dealt by HICC team alone. In certain cases, an Outbreak control committed (OCC) should be convened as per hospital policy's) e.g. if the outbreak is large or serious or ii)If the microorganism is unusual.

- The members of OCC include: administrator, treating clinician, HICC team, epidemiologist, microbiologist and the public relation officer.
- Role: The OCC performs the following actions:

- A detailed outbreak control plan should be drawn ,clearly addressing the areas of individual responsibilities, and action plans for all involved.
- Facilitates the investigation of the outbreak.
- Implement and monitor various control measures which may include:
  - ♣ Full implantation of infection control measures as recommended by HICC.
  - ♣ Special nursing procedures including isolation of cases.
  - ♣ Closure of health care facilities, if necessary.
  - ♣ Special cleaning and disinfection procedures.
  - ♣ Closure of catering facilities, if considered appropriate.
- Oversee communication to all relevant groups.
- Facilitate the medical care of patients with the involvement of relevant clinical team.

- A special incident room must be set up to coordinate the outbreak if feasible
- Where there is a major incident, the OCC should seek advice from experts at both regional and national levels

Table: Summary for investigation of an outbreak

Steps	**Suggested approach**
Step 1.Recognise outbreak and prepare to investigate	
Determine the existence of the outbreak	• **Ascertaining the reliability of both clinical and laboratory information** • **Ruling out of pseudo-.Look at changes that may have affected the rate of infection-new staff, new procedures , new laboratory tests ,staff, patient ratio, etc.,** • **Establish background rate of diseases and HAI surveillance data-FIND out if observed number of cases is in excess than usual** • **If outbreak is not confirmed – then the HICC team must inform the clinical team who have reported the outbreak and provide reassurance.**

Determine if immediate control measures are needed	**HCWs should be advised:** • **Reinforce standard precautions** • **Apply appropriate transmission-based precautions**
Notify and communicate	• **HCWs in the immediate area** • **HICC if not notified still** • **Administrators** • **Laboratory for further testing for epidemiological typing** • **IDSP i.e. integrated disease surveillance programme(if it is Notifiable disease)**
Formation of an outbreak control committee(OCC)	**Membership may include but is not limited to:** • **Administrators (medical and nursing)** • **Clinical/in- charges/managers of implicated areas** • **Officer in-charge,HICC** • **Clinical microbiologist** • **Infectious diseases physician/epidemiologist** • **Public relation officer** • **Others as defined by circumstances** **Lead investigator or 'chair' is nominated**
Conform the diagnosis	• **Review laboratory data and request additional laboratory test if necessary** • **Full microbiological investigation if anything is left** • **Phenotypic typing** • **Molecular typing of organisms to confirm clonality** • **Are there more cases than expected compared to previous weeks/months** • **Review scientific literature** • **Consider epidemiological of cases- are there two or more linked cases of the same illness?**

Step 3.Establish case definition and find cases	

Establish a set of standard criteria to decide whether or not a person has the disease of concern.	• **At the start of an outbreak , use a broad case definition and then narrow the case definition sown at a later date when more information is available from the clinical and laboratory investigation.**
	• **Cases can be classified as**
	  ○ **'Confirmed'(usually laboratory verification);**
	  ○ **'Probable'(usually has typical clinical features);**
	  ○ **'Suspect'(usually has fewer typical clinical features)**

Find cases	**Gather critical information by;** • **Taking history from suspected cases and their contacts** • **Follow –up of confirmed cases in hospital and those who are discharged**
Identify and count cases	**Collect the following types of information** • **Identifying information** • **Demographic information** • **Clinical information** • **Risk factor information(including environmental tests)**
Develop Line listing of cases	**This should be based on-** • **Time-date of onset illness** • **Person –age, sex** • **Place –where did the exposure occur?** • **Other relevant information**
Create epidemic curve to determine hypothesis	• **Number of cases on y- axis** • **Time on x- axis**
Step 4. Initiate precautionary	

measures	
Initiate precautionary measures	• **Use of standard precautions and appropriate transmission – based precautions** • **Environmental cleaning using appropriate products** • **Prophylactic treatment/immunization** • **Antibiotic restrictions** • **Exclusion of cases from high risks activities** • **Isolation and/or cohorting of patients** • **Restricting movement of patients ,staff and visitors** • **Screening of patients with isolation of patients and cohorting of contacts** • **Provision of health information and advice**
Step 5.Develop and test hypothesis- the 'how 'and 'why'	

Steps in Outbreak Response

Step 1 - Verification of the outbreak

1. Identify validity of source of information – to avoid false alarm / a data entry error
2. Check with the concerned MO:
   - If there is an abnormal increase in the number of cases or
   - If there is a clustering of cases or
   - If the cases are Epidemiologically linked or
   - If some trigger events have occurred (see above) or
   - If many deaths have occurred.
3. The DSO should alert the neighbouring district/CHC/PHC about the outbreak so that preventive measures can be instituted there also.
4. DSO will notify the concerned Programme officer and the CMO about the outbreak.
   The concerned Programme division will take further control measures.

The Outbreak Response Team (ORT):

The ORT is a multi-speciality team that provides assistance in the management of an outbreak.

- Composition:
  - An epidemiologist,
  - A clinician and;
  - A microbiologist.
  - Other specialists as per requirement. Roles and functioning:
  - Investigation and confirmation of outbreak
  - Assist local health staff in controlling the outbreak
  - Follow up of control measures undertaken
  - It works in coordination with the DSO/CMO/concerned Programme divisions and MO/local health staff.

Step 2 – Sending the ORT

- A ORT should be immediately constituted from the panel of specialists according to the suspected type of outbreak.
- Orientation of the ORT to the current scenario.
- Resources (vehicles, drugs, reagents and forms) should be made available to the ORT to move to the affected area.
- Coordination and feedback from ORT.

  The ORT would investigate the outbreak in the following manner and report to the DSO/concerned Programme officer/CMO.

- The ORT should file an interim report. A format is given in Annexure
- If the epidemic continues unabated, consider action regarding special studies as per the figure below
- Follow-up visits should be undertaken to ensure that the control measures are being implemented adequately.

To Investigate or control?

		SOURCE / TRANSMISSION	
		Known	Unknown
AETIOLOGY	Known	Control +++ Investigate +	Control + Investigate +++
	Unknown	Control +++ Investigate +++	Control + Investigate +++

Step 3: Monitoring the situation

ORT will update the DSO on the progress of control measures/state of outbreak. This will be done in liaison with the CMO/concerned Programme officer. The main points to monitor are:

This should continue till the outbreak is officially declared to be over.

- The trends in the cases and deaths.
- The containment measures that are being implemented
- Drugs / vaccine stock
- Logistic issues – communications, vehicles,
- Community involvement
- Media response

Step 4: Declaring the outbreak to be over

When there have been no new cases for a period of 2 incubation periods since the onset of the last case (after rigorous active case search).

Step 5: Review of the final report

To be submitted within 10 days of the outbreak being declared to be over. The Technical committee should review and make suitable recommendations – immediate and medium term, so that similar outbreaks do not occur in the future.

The hospital takes appropriate corrective action to prevent the recurrence

Control measures

A - General control Measures

Even as the outbreak is detected, and is being investigated, control measures need to be instituted.

General measures - till the specific source and route of transmission is identified. For example, if one is suspecting water borne disease, then one should start a campaign-requesting people to use safe drinking water.

Response to an outbreak requires additional input of following resources.

- Human resources - Additional MO's, lab technicians and nursing staff.
  Drugs –Mobilization of medicines from other sources/locations.
- Equipment and supplies
  Vehicles and mobility
- 24-hours Communication channels have to be established between the District and the team leader at the outbreak location.

IEC: To sensitise the community about the problem and to dispel rumours and misinformation.
More details are given in Annex

- Handling of the media: Given the impact of the media on the people. Only a designated person should deal with the media regarding the status of the outbreak.

B - Specific control measures

Specific control measures are instituted on the basis of nature of agent and characteristics of the high-risk group and the possible sources. These measures may include:

- Identification and elimination of the contaminated product;
- Modification of nursing procedures;
- Identification and treatment of carriers, and
- Rectification of lapse in technique or procedure

Evaluation of efficacy of control measures

• The efficacy of control measures should be evaluated by a continued follow-up of cases after the outbreak clinically as well as microbiologically. Control measures are effective if cases cease to occur or return to the endemic level.

• The outbreak should be documented.

Control Measures for Specific Types of Outbreaks

(a) Water Borne Outbreak

Ensure the following

- **Access to safe drinking water:**
  - No consumption of water from affected sources till it is made safe for consumption.
  - Alternate supply of safe water should be arranged.
- **Sanitary disposal of human waste:**
  - Frequent hand washing.
  - Adopting safe practices in food handling.

(b) **Vector Borne Outbreak**

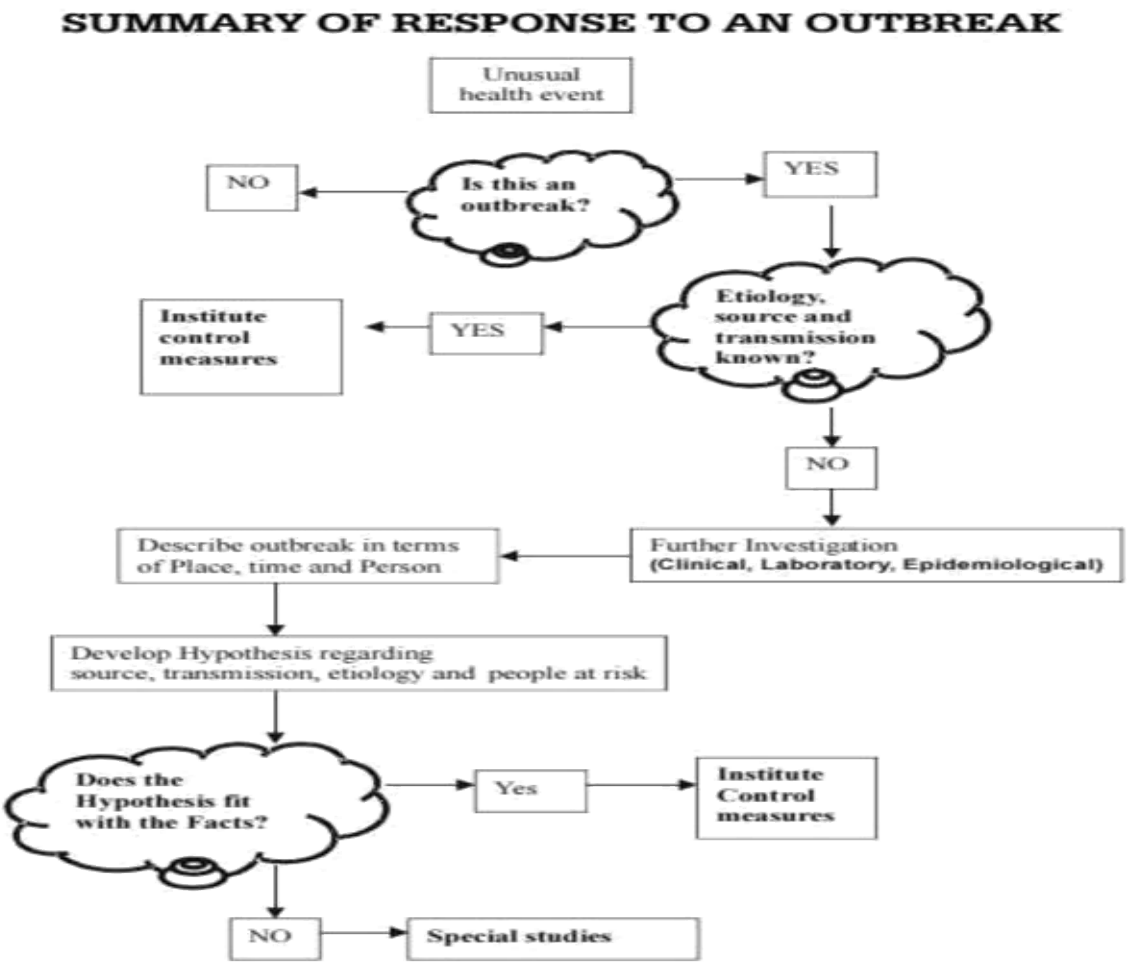
Ensure the following:

Vector control: Integrated vector control methods should be implemented on priority under guidance by the entomologist (if available).

- Use of environmental methods (draining of water collections/ stagnation, filling, etc)
- Biological (use of larvivorous fish, Bacillus thuringensis, etc) and
- Chemical (larvicidal – abate/ baytex, anti-adult-space sprays, fogging only if absolutely essential, and indoor residual spray with appropriate chemicals)
- Personal protective measures: Prevention of exposure to mosquito bites by using repellents (including neem oil) and use of mosquito nets at night (plain or impregnated) would significantly reduce risk of infection during an outbreak.

(c) Vaccine Preventable Disease Outbreak

- Adequate supply of vaccines, syringes and needles
- Adequate staff who are able to administer the vaccines.
- Ring immunisation wherever applicable.



Outbreak of Unusual Syndromes Leading to Death or Hospitalization

Why Surveillance of Unusual Syndrome?

While most common illnesses fit into the syndromic approach, the health workers should be alert for uncommon events in the community also so as to detect new/emerging etiologies of outbreaks.

Syndrome Description: The sudden occurrence of unusual events, in a geographical region, causing death or hospitalization and which does not conform with the standard case/syndrome definitions under the existing surveillance mechanisms. Some of the symptoms may be:

- Convulsions
- Alteration in consciousness
- Breathing Difficulty
- Bleeding
- Paralysis
- Others

Trigger: Two cases of death or hospitalisation due to an unusual symptom.

Reporting

The purpose of reports is:

1. To keep the authorities at the higher level informed so that they can make the appropriate decisions.
2. To help to review the outbreak and response, identify system failures and take corrective measures so that similar events are prevented.

Interim report by ORT

The ORT will submit an interim report within one week of starting their investigation, response and control activities. The report should cover verification of the outbreak, total number of affected cases/ deaths, time, person, place analysis, management of the patients, likely suspected source, immediate control measures implemented, etc. The report will include reports by the physician and microbiologist, and entomologist (where applicable). The lab results received during that period, environmental factors, etc. It will also have a provisional hypothesis of the causation of the outbreak and comments/recommendations, if any, including whether any further outside help is necessary.

Final report

Within 10 days after the outbreak has ceased, a final outbreak investigation report must be submitted by the local health authorities.

- This report must be comprehensive and give a complete picture of the multi-factorial causes of the outbreak, the precipitating factors, the evolution of the epidemic, description of the persons affected time trends, areas affected and direction of spread of the epidemic.
- It should have complete details of lab results including regional lab (cross verification and strain identification), confirmation of the provisional diagnosis and other relevant information.
- It is important that feedback from the report is shared with the lower levels and also other districts.
- Publication in a journal will ensure wider dissemination of results & direction of spread of the epidemic.
- It should have complete details of lab results including regional lab (cross verification and strain identification), confirmation of the provisional diagnosis and other relevant information.

- It is important that feedback from the report is shared with the lower levels and also other districts. Publication in a journal will ensure wider dissemination of results.

SUMMARY OF OUTBREAK INVESTIGATIONS

Response by Health Worker

S.No	Syndrome	Trigger event	Action taken
1	Acute watery stools	A single case of severe dehydration /death in a patient > 5 years of age with diarrhoea. More than 10 houses having at least one case of loose stools irrespective of age per village or an urban ward	1. Treat with appropriate antibiotics. 2. Treat with ORS Refer to SVIMS if dehydration is 3. severe. 4. Inform MO. 5. Collect water samples and send to Lab for analysis. 6. OT testing 7. Check TCL stock (bleaching Powder) 8. Train the local person/s about chlorination of water. 9. IEC for community awareness about safe water and personal hygiene.
2	a) Fever < 7 days duration Only fever	5 cases in 1000 population.	1. Slides for MP with presumptive /RT for malaria 2. Inform MOPHC. 3. IEC for community awareness.
	b) With rash	Two similar cases in a village	1. Collect slide for MP.

	(Measles / Dengue)	(1000 population)	2. Refer the case to SVIMS 3. Inform MO SVIMS

			4. Give vitamin A 5. Give paracetamol. 6. Check immunisation 7. Surveillance for Aedes Egypti Larvae in the house. a. Containers b. Coolers, etc
	c) Altered consciousness	Two cases of fever with altered consciousness in the village / 1000 population	1. Collect slide for MP. 2. Refer the case to SVIMS 3. Antipyretics (Avoid Aspirin) 4. Inform to ORT 5. IEC
	d) Fever with bleeding	Two cases of fever with bleeding in a village or 1000 population	1. Refer the case to SVIMS 2. Inform to ORT 3. IEC
	Fever with convulsions	Two cases fever with convulsions in a village or 1000 population	1. Refer the case to SVIMS 2. Inform to PHC 3. IEC
	Fever more than 7 days	More than 2 cases in a village or 1000 population	1. Give paracetamol. 2. Collect slide for MP 3. Give anti malarial treatment. 4. Inform and refer to SVIMS for treatment.

			5. OT testing of drinking water. 6. Collect water sample and send it to Lab for onward transmission.

S.No	Syndrome	Trigger event	Action taken
			7. Check TCL stock. 8. Train local person about water Chlorination. 9. Community awareness about safe water and Personal hygiene.
3	Jaundice	More than 2 cases in a village or in 1000 population.	1. Refer to SVIMS 2. Inform MO SVIMS Search and refer antenatal cases 3. with jaundice in $2^{nd}/3^{rd}$ trimester. Collect water samples for analysis 4. and send it to Lab 5. OT testing of drinking water. 6. Collect water sample and send it to Lab for onward transmission. 7. Check TCL stock. 8. Train local persons about water Chlorination. 9. Community awareness about safe water and Personal hygiene.
4	Unusual event	More than 2 deaths or	1. Inform MO SVIMS

		hospitalization	2. Community awareness

Policy on CSSD

Purpose:

- The purpose of the Central Sterile Supply Department is to make reliably sterilized articles available at the required time and place for any agreed purpose in the Hospital as economically as possible, having regard to the need to conserve the time of users.

- To provide sterilized material from a central department where sterilizing practice is conducted under conditions, which are controlled, thereby contributing to a reduction in the incidence of hospital infection.

- To take some of the work of the Nursing staff so that they can devote more time to their patients.
- To avoid duplication of costly equipment's, which may be infrequently used.
- To maintain record of effectiveness of cleaning, disinfection and sterilization process.
- To monitor and enforce controls necessary to prevent cross infection according to infection control policy.
- To maintain an inventory of supplies and equipment.
- To stay updated regarding developments in the field in the interest of efficiency, economy, accuracy and provision of better patient care.
- To provide a safe environment for the patients and staff.

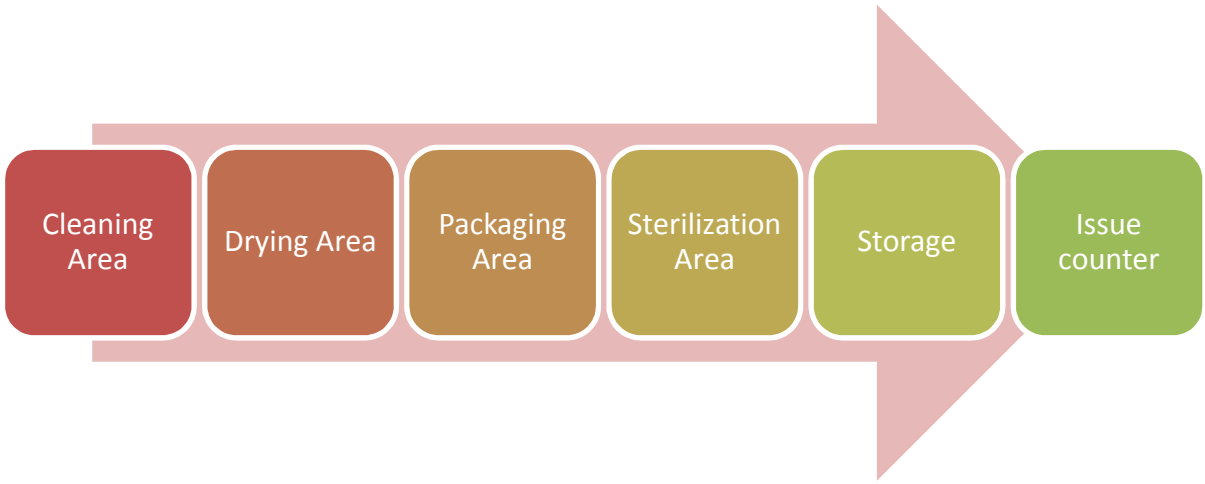
Scope: It is a centralized department catering to the sterilization need of the entire hospital.

Designing of a CSSD:

The workload in a CSSD varies from hospital to hospital. The size and location usually depends on the number of, the hospitals the CSSD will serve as well as the number of beds and the future expansion of the hospital. However 6 to 10 square feet per bed is recommended as an area of requirement for the CSSD. It should be located as close as possible to the major user areas such as Operation theatres, Accidents and Emergency department and wards.

The processing of the workflow should always be unidirectional; from an unsterile area to a sterile area. Physical barrier is a must to separate the decontamination area from other areas to prevent contamination.

There should minimum six basic divisions in CSSD



Transport of items:

- Sterile and dirty/non sterile items should be transported separately via two dedicated lift/dumb waiter. Across the building transportation should take place via two separate closed vehicles.
- The dirty goods and sterile goods should always be kept in separate closed container in dedicated trolley during transportation.
- At CSSD, the receptions of dirty goods and sterile goods should be located far away from each other, in the decontamination area and sterile area respectively.
- Personnel handling the items should wear gloves, gowns and masks.

Decontamination area:

Reception- CSSD should have a reception in decontamination area to receive all dirty goods.

- CSSD personnel should treat all items as contaminated and potentially infectious.
- Items should be checked for removal of gross dirt, completeness of set and damage
- Visibly dirty, incomplete/damaged instruments may be returned by CSSD
- Sharps must not be picked up with gloved hands; forceps can be used for this purpose.
- Received items may be documented on Received Note / Ledger.

Infrastructure

- Ceilings and walls should be made up of non-shedding material which can tolerate harsh chemicals
- The surfaces should be smooth and non fibre shedding.
- Floor drains are required with appropriate slopes for effective drainage after washing.
- Proper lighting is of utmost importance for proper inspection as well as cleaning.
- A table for receiving used instruments, sinks, and racks for draining should be provided in this area.
- The wash basin for hand wash station and instrument cleaning must be separate.
- Should have a minimum of 10 air exchanges per hour, negative air flow and be exhausted outdoors without re-circulation.
- There should be a pass through window lo packing area. No other communication should be there.

b.Procedure guides for cleaning, packing, disinfection, sterilization, storing and issue of the items*

Pre-soaking and pre-cleaning:

- Pre-soaking or pre-cleaning in enzymatic solutions is essential step needed to loosen the debris. Keeping the debris on the instrument moist by using a pre-soak makes the cleaning process more efficient.
- Pre-cleaning/soaking in patient-care areas is needed on items that are heavily soiled with feces, sputum, blood, or other material. No items should be sent to CSSD while visible dirt/soil.

Cleaning:

- **Sorting out-** Items can be segregated according to the method of cleaning (manual, ultrasonic or washer / disinfector.) The containers also need to be cleaned each time.

- **Disassembly-** Instruments and other items composed of more than one part or piece should be disassembled to expose all surfaces to the cleaning process
- **Cleaning agents** with low foaming surfactants should be used during manual cleaning procedures to ensure that instruments are visible in the cleaning solution.
- Do not place heavy instruments on top of delicate devices.

Methods of Cleaning

- Manual cleaning
- Automatic cleaning: Ultrasonic washers, Washer disinfector and Endoscopic reprocessing

Manual washing:

- Manual cleaning is recommended for some devices which are i) temperature sensitive, ii) solution sensitive, iii)size limitation, iv) Mixed metals and v)electronic and non immersible devices, vi) for fragile or difficult-to-clean instruments.
- Ideal sink size is 36" high, 8-10" deep and wide enough to allow instrument trays to lay flat.
- It should have 3 sinks to put all dirty goods to wash.
    - *Soaking sink* (first): Enzymatic cleaner to soak instruments
    - *Washing* sink (second): Washing and scrubbing/brushing
    - *Third sink for Rinsing.*
- *Brushing*- Soft-bristled, nylon brushes and pipe cleaners should be used. Metal brushes or scouring pads must not be used as they damage the surface of instruments.
    - Brush of appropriate type, size, bristle type and material should be used.
    - Brushing followed by flushing with the cleaning solution and then flushed, preferably with treated water, to remove chemicals and/or debris remaining
    - *Brush underwater*- Immersible devices should be cleaned under water to minimize aerosolization.

Washer disinfector:

- The washer disinfector has the ability to wash, rinse, dry and disinfect the goods or instruments.
- They typically contain a rotating spray system plus a glass door for inspection.
- The temperature will range from 40 to 100°C.
- Ideal is a *from operated double door -washer disinfectant*- loaded through one door and unloaded through the other side to packing area thereby preventing contamination

Ultrasonic washers:

- Ultrasonic cleaning as the most effective way to clean surgical instruments, particularly those with hinges, box locks, and other moving parts.
- Ultrasonic cleaning removes soil by cavitation and implosion in which waves of acoustic energy are propagated in aqueous solutions to disrupt the bonds that hold paniculate matter to surfaces.

Automatic Endoscopic reprocessing system:

- It is an automated system for endoscopes cleaning and drying.
- Detail has been discussed in disinfectant section.

Cleaning agents

- For instrument cleaning, a neutral or near-neutral pH detergent solution commonly is used.
- Enzymes, usually proteases, lipases, and amylases sometimes are added to neutral pH solutions.
- Enzymatic cleaners are not disinfectants, and proteinaceous enzymes can be inactivated by germicides.

Rinse Water

- For manual cleaning- Treated water (e.g., deionized, distilled, or RO water) is preferred for the final rinse since it prevents staining and contamination of instrumentation.
- Automated washers can provide a final rinse with whatever grade of water is made available.

Drying

After washing, instruments need to be dried as water droplets would interfere with most of the sterilization processes.

- In steam sterilization- excess water would not be re-vaporized after the process, causing wet packs.
- EO reacts with the water molecule and the concentration of gas is reduced.
- In case of gas plasma, the cycle is aborted if any moisture is present in the load.
- The only exception is water droplets left in the lumen of articles which facilitates steam penetration.

Drying is achieved by

- Keeping the items to air dry in a clean, dust free place away from the floor. This is not very practical as drying takes a long time.
- Clean pressurized air can be forced over the instruments and through lumens

- Items can be wiped with a clean, non shedding cloth manually.
- Items can be dried in a hot air oven with a thermostat and air circulation facility to maintain a fixed uniform temperature. This is the **best method** as it does not involve manual handling of the device after cleaning, as well as saves labor.

Preparation and packaging area:

Packing is a step in the sterilization process in which a medical device is enclosed in materials or a container designed to allow the penetration and removal of the sterilant during sterilization and then to protect the device from contamination and other damage following sterilization and until the time of use.

Assembly of instruments

- Place instruments on the tray over the porous material and always with the pivots and automatic grips open
- Instruments should be arranged in a definite and orderly manner and not crowded together. If possible, instruments should be presented in order of use.
- Heavy items must be placed at the bottom to avoid damaging delicate ones.
- Avoid piling instruments one upon the other.
- More is the metal mass; more is the condensation that occurs.
- Sharp and micro instruments should be protected by means of holders, tip guards or foam which is permeable to the sterilant being used, (according to manufacturer recommendations)
- Instruments with removable parts should be *disassembled* for better penetration of steam.
- No linen pack should be above the maximum size (12" x 12" x 20").
- Maximum weight of any set should not exceed 10 to 12 kgs.
- Packages must be loosely packaged, yet secure.

Packaging Techniques

Peel Pouches

Disassemble and open items so that sterilizing agent can reach every surface

- Fill pouch up to $^{3}/4$ of the capacity and remove residual air before sealing
- Protect tips so they do not puncture pouch
- Place item into pouch so the end user can grasp the instrument properly to aseptically remove from the pouch
- When double peel pouching, seal the inner package first then place in second pouch and seal. Never fold the inner pouch.

Instrument Sets

- Place instruments on the tray over the porous material and always with the pivots and automatic grips open
- Package the objects loosely. Avoid over loading the sterilizer. Do not allow packages to come in contact with the interior walls

Fabric Packs

- Vertical position is recommended as it favours the output of air and the pathway of water-vapour
- Horizontal position makes it difficult for the air to move out and the water-vapour to go through

Packing material:

Packing should be done with materials which is capable of wrapping, package and contain reusable supplies and medical devices for sterilization, storage and aseptic preparation for use.

For ideal packing: The packing material should be

- Must be permeable to the sterilizing agent (steam, ethylene oxide, dry heat or gas plasma).
- Excellent barrier qualities.
- Must allow adequate air removal from packaging and contents
- Must allow adequate release and removal of the sterilizing agent at the end of the cycle
- Withstand the physical conditions (temperature, moisture, pressure or vacuum) of sterilizer.
- Must not contain any toxic materials or dyes which may cause reaction to handling personnel
- The packaging material must allow the package to be opened with minimum risk of contamination by fall-out of particulate matter or lint and allow aseptic removal of the contents to a sterile field.

Types of packing material:

Mainly three types of packing materials are used:

- Woven fabrics
- Non-Woven items: fabrics, plastic wrappers, papers, peel pouches
- Rigid containers

Table: Types of packing materials

Woven fabrics *(e.g. Linens)*	**Types-** • Natural fibres of cotton (called linen) or • Blends of cotton and synthetic material such as polyester **Uses /properties-** • Can be used for steam, and LTSF. • It is *not recommended for EtO, plasma and dry heat,* • They *do not have good barrier properties* and these further diminish by repeated sterilization and laundering • Linen should have a *thread count of 140.* • Prior to each use they require laundering and inspection for holes, worn spots and stains. • They often need to be repaired. Stitching should never be used for mending of holes. • To enhance barrier qualities a double wrap is recommended
Non-Woven fabrics	• They are made by methods other than weaving. • Fibers are pressure bonded to form sheets of fabric. • They are designed as single use products, *they cannot be reused.* • They have *excellent barrier properties* • They are the flexible and stretchable, but can be torn or punctured. • They are *suitable for steam, LTSF, EtO and gas plasma* • They are virtually lint free and resist liquid penetration, although they do provide excellent water vapour transmission. • As non absorbent, they may retain water condensation
Flat wrappers	• Most versatile wrapping material sheets • Available in various sizes ranging from 8"x8" to 54"x54" • *Two types of foldable wrappers available-* o Envelope (Diagonal) fold o Square fold
Papers	• Paper lacks the flexibility of non woven fabrics. • They can only be used for small, light, porous or soft items. • Used for steam, EtO, LTSF and dry heat but *not for plasma* • They do not have good wet strength and tear easily

	• 60 GSM thickness is recommended. • *3* Types. i) Craft paper, ii) Crepe paper (stretchable), iii) Glassine paper.
Peel Pouches: *i) Plastic-plastic pouches* *ii) Paper-plastic pouches*	Peel pouches are used for light weight items and when it is necessary to see what is inside. Minimum thickness of plastic layer is 2mm. • *Two types:* o Plastic-Plastic pouches- can be used in all sterilizers o Paper-plastic pouches - cannot be used for EtO • *If double punching used:* The inside pouch must have no folded parts and should face plastic to plastic and paper to paper with respect to the outer pouch. • *Label* only on the plastic side with a felt tip marker (not ink pen) as writing on the paper side may cause damage to the package. o Sealing- has to be continuous, end to end and tightly secured, o Self sealed pouches- Check for entire edge is securely fastened. o Before sealing, air should be removed as much as possible. • *Handle of the item*- Pack in manner that handle of the item should be near to the seal- easy to grasp while using • *Peel pouch should never be kept inside a container* as it interferes with air removal steam penetration. • *While placing in sterilizer.* o Place adjacent to each other, with paper to plastic o Not to be placed one above the other • *Post-sterilization* o Check the pouches *for moisture* before being put into storage, o Pouch is considered *sterile until it is opened.* • Only products with *PDA 510 K clearance* should be used
Rigid instrument containers	• They come in various sizes and designs or box like structures with scalable, removable lids. • They are constructed of anodized aluminum, stainless steel, high temperature plastics or combinations of these.

	• They have perforations in the top lid, covered internally by sterilant permeable microbial filters. • Recommended for plasma sterilization

*LTSF- low temperature steam / formalin, EtO-Ethylene oxide

Labeling: Labeling is done by either manual or label gun

- Date of sterilization & expiry
- Identification of sterilizer
- Load number, Operator
- Package contents
- Initials of employee who prepared package

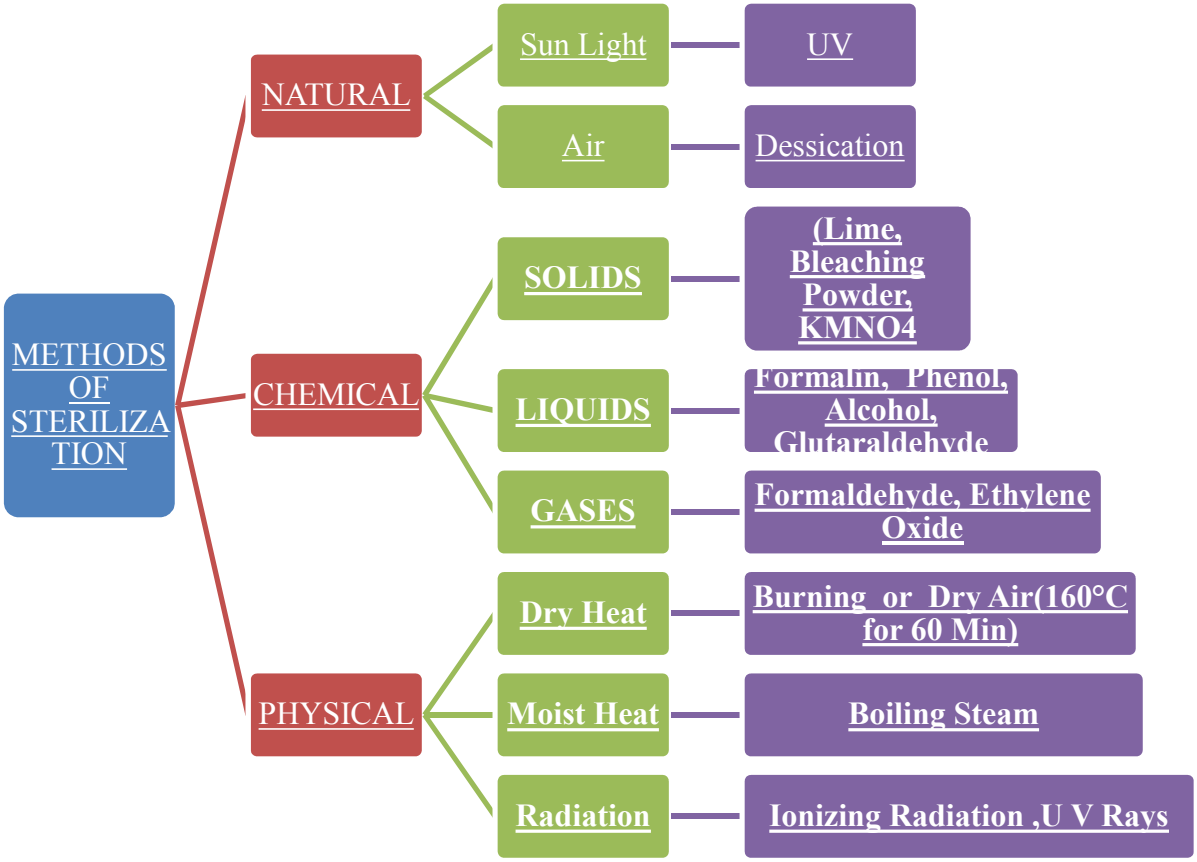
Sealing:

- Packages can be closed by heat sealing or tape sealing.
- Sealing has to be continuous, end to end and tightly secured.
- Self sealed pouches - Be sure that the edge of the plastic is securely fastened.

Points to remember while loading on the sterilizer

- Place surgical instrument trays flat on the sterilizer shelf to maintain even instrument distribution and facilitate drainage.
- Lighter items on top and heavier items on bottom shelf.
- Peel packs should be placed plastic to paper kept adjacent and not plastic to plastic.
- Avoid overloading of sterilizer as this inhibits steam penetration and air removal
- Do not allow items to touch chamber wall where they may come in contact with condensate.
- Check for soils left over on the surfaces- this may prevent direct contact with steam.
- Dry items only
    - Items must be dry before packaging. Additional water may produce wet packs.
    - In addition, water can act as an insulator and can prevent good heat transfer
- Not placing basins on their edges & not using non-linting absorbent material between nested basins can prevent air removal and steam penetration.
- Bottles like containers that can hold water, should be placed on their side to facilitate air removal and water draining out. If placed upright, air may be entrapped in them.
- Position textile packs with the layers perpendicular to the shelf.
- Instruments should not be held together using rubber bands.
- Devices with lumen like catheter, suction tubing should have their stylets or plugs removed and should be flushed with distilled or de-ionized water just prior to packaging and sterilization. The moisture in the lumens will generate steam within the lumen.

- Instruments with rachets should be in unlocked position.
- Racks, pins or stringers can be used to hold instruments in open position.
- Devices with removable parts should be dissembled as per manufacturer instructions.
- If linen used as wrapping material- Staining on instruments may occur if linen is not completely rinsed.
- Discoloration of instruments - Impurities in steam due to excessive use of chemical in boiler may cause spotting on packs and staining / corrosion on instruments.



Sterilization area:

Double door sterilizers should be used whenever feasible, one door side facing packing area and the other side facing sterilization area or storage area.

Sterilizers used in CSSD are: i) Autoclave/steam sterilizer, ii) ETO, iii) Gas plasma sterilizer

Steam under pressure (Autoclaves)

- ***Types of stem sterilizers***
    - Gravity air displacement Sterilizers
    - Pre-vacuum Sterilizers- mostly used now a days
    - Steam Flush Pressure Pulse (SFPP) Sterilizers.
- ***Sterilization cycle:***
    - *Conditioning*- First, steam enters into chamber and strikes a baffle plate to prevent the steam directly heating the load. Air is displaced by steam from the load & chamber.
    - *Exposure*: After desired temperature is reached, Load is held at a specific temperature and pressure for a time known to provide effective sterilization.
    - *Exhaust*: In this phase, steam is removed through drain. Steam passing through drain, condenses into water by a special mechanism. This creates a slight chamber vacuum which facilitates entry of hot sterile filtered air through a special filter,
    - *Drying:* hi drying phase, hot filtered sterile air is introduced in chamber to re-vaporize any liquid water & to remove it from the load and chamber.
- ***Uses:***
    - It is the most efficient and reliable method of sterilization (wide margin of safety).
    - Use for sterilization of all critical and semi-critical items that are heat and moisture resistant (surgical instruments, surgical drapes, some respiratory and anesthetic equipments, microbiological waste and sharps).
- ***Advantages:***
    - It is low cost than EtO and plasma
    - Sterilization cycles are fast compared to EtO
    - It is non toxic and leaves no byproduct behind
    - It is relatively simple technology
    - Easy to control and monitor.
    - Compatible with most type packing materials
- ***Disadvantages:***
    - Heat can damage acrylics and styrene, PVC, and corrode some metals with excessive heats.
    - The effectiveness of steam sterilization increases with higher temperature but using higher temperature for prolonged time can harm or shorten the life of instruments.
    - Moisture also can adversely affect electronics and can cloud some materials or leave water mark stains on them.
    - Prion sterilization is challenge - Recommended temperatures are:
        - ♣ 121°C - for 4.5 hours (Gravity displacement sterilizers)
        - ♣ 132°C for 60 minutes (Gravity displacement sterilizers)
        - ♣ 135°C for at least 18 minutes (Pre-vacuum Sterilizers).

- ***Monitoring:*** Monitoring the holding time, steam quality, temperature and pressure of the sterilizer is essential to ensure sterilization efficacy. It is described below.

Ethylene oxide sterilizer: Ethylene oxide is a gaseous, low temperature sterilant.

- ***Principle:*** It is an alkylating agent, acts by alkylating and there by breaking down microbial DNA.
- ***Steps:*** The basic ETO sterilization cycle consists of four stages: total duration is 12-24 hours.
  - *Preconditioning and humidification*- Items to be sterilized are heated at low temperature (37-63°C), and humidified (40-80%)
  - *Initial evacuation;* A deep vacuum is applied to the chamber to remove all the air.
  - *Gas exposure:* ETO at concentration (450-1200 mg/L) is introduced for exposure time of 1 -6 hours.
  - *Evacuation and Air cycle*- Removal of gas from the chamber till it falls below the flammable limit with replacing with fresh air. This takes an additional 8-12 hours.
- ***Uses/advantages:*** EtO is used for heat and moisture labile critical and semi-critical items such as
  - Devices that incorporate electronic components, plastic packaging or plastic containers.
  - Assembled complex devices
  - Catheter and stents
  - Wound dressings
  - Multi lumen tubings
- ***Precautions/disadvantage:***
  - EtO gas must penetrate the entire load
  - Items must undergo aeration to remove residual EtO
  - Pure form is flammable and explosive even when allowed to mix with a little air
  - Ensure regular environmental monitoring, employee training and medical examination.
  - Warning signs must be posted near EtO plants. Only authorized persons should enter the area.
  - Effectiveness altered by lumen length, lumen diameter, inorganic and organic contamination.
  - Potential hazard to patients and staff(allergies/neuropathies/known carcinogen)
  - Lengthy cycle/aeration time
  - Linen should not be used for packaging.

Gas plasma sterilizers:

Plasma sterilization is a recently introduced sterilization method (e.g. Sterrad system).

- ***Principle:***

- Gas plasmas are referred to as the fourth state of matter.
- They are generated by exciting a chemical precursor (H_2O_2 alone or mixed with peracetic acid) under a deep vacuum in an enclosed chamber using radiofrequency/ microwave energy,
- This produces highly reactive and biocidal charged particles, many of which are free radicals.
- The free radicals react and inactivate essential cellular components (enzymes, nucleic acids) of microbes.

- ***Steps:*** *Total time (o sterilization process is* 47-75 minutes
  - *Evacuation and replacement*- The sterilization chamber is evacuated and H_2O_2 solution is injected from a cassette and is vaporized in the sterilization chamber to a certain concentration.
  - *Diffusion of vapour*- The H202 vapor diffuses through the chamber, exposes all surfaces of the load to the sterilant.
  - *Free radicals*- An electrical field created by a radio frequency is applied to the chamber to create a gas plasma. Microbicidal free radicals are generated in the plasma which destroys the microbes.
  - *Removal of excess gas*- The excess gas is removed. The sterilization chamber is returned to atmospheric pressure by introduction of high-efficiency filtered air.
  - *Aeration not required:* The by-products of the cycle (e.g., water vapor, oxygen) are nontoxic and eliminate the need for aeration. Thus, the sterilized materials can be handled safely, either for immediate use or storage.
  - If any moisture is present on the objects the vacuum will not be achieved and the cycle aborts.
- ***Precautions:***
  - Items should be totally dried before loading.
  - H_20_2 may be toxic at levels greater than 1 ppm TWA (time weighted average)
  - Linen or paper or cellulose or liquid cannot be processed.
  - Requires synthetic packaging (polypropylene) and special container tray
  - It may not penetrate well, especially in channels or devices designed with long lumens.
  - Small chamber- cannot be used for bulk items
  - Expensive equipment and packing materials

- ***Uses:***
  - Sterilization of devices which are heat and moisture sensitive (plastic, electronic devices, corrosion sensitive metals).

- Examples: Arthroscope & its instruments, micro instruments, vascular instruments, spine sets, laparoscope and its instruments.

Storage area:

- It is the equipment warehouse for the entire hospital.
- Designed to store sterile items before their selection and distribution for use in procedures
- There should be *positive airflow* from the sterile area to other areas
- Protect sterile items from inadvertent contamination and environmental challenges
- Entry should be strictly restricted
- Reception area should be partitioned from the rest of the storage area and window operated to deliver the goods.
- Issue of items to respective Operation theatres, ICU's, recovery rooms, wards e.t.c.

c. Reprocessing of instruments and equipments

Definitions

Table: Definitions of Sterilization and disinfection

Sterilization	Process by which all living microorganisms, including viable spores, are either destroyed or removed from an article, body surface or medium It results in reduction of 10^6 log colony forming units or microorganisms and their spores. It can be achieved by physical agent or a chemical agent.
Disinfection	It refers to a process that destroys or removes most if not all pathogenic organisms but not bacterial spores. It leads to reduction of at least 10^3 log colony forming units of microorganisms, but not spores. The primary goal in disinfection is to destroy potential pathogen, but it also substantially reduces the total microbial population.
Asepsis	It is a process where the chemical agents are applied on body surfaces, which kill or inhibit the microorganisms present on the skin. They prevent entry of the pathogens into sterile tissues and thus prevent infection or sepsis They are generally not as toxic as disinfectants as they must not destroy too much of host tissue.
Decontamination or Sanitization	It refers to reduction of pathogenic microbial population to a level at which items are considered as sage to handle without protective attire. It results in reduction of least 1 log colony forming units of most microorganisms but not spores

Spaulding's classification

Earle H. Spaulding devised a rational approach to classify the patient – care items and equipment into four categories (table) according to the degree of risk for infection involved in use of the items. This classification scheme is so clear and logical that it has been retained, refined and successfully used by infection control professionals in the hospital.

Table: Spaulding classification of medical devices

Medical device	Definition	Examples	Recommended sterilization/ Disinfection method
Critical device	Enter a normally sterile site	Surgical instruments, cardiac and urinary catheters, implants, eye and dental instruments	Heat based sterilization chemical sterilant or High-level disinfectant
Semi-critical device	Comes in contact with the mucus membranes or minor skin breaches	Respiratory therapy equipment, anesthesia equipment, endoscopes, laryngoscope, rectal/vaginal/esophageal probes	High level disinfectant
Non – Critical devices	Comes in contact with intact skin	BP cuff, ECG electrod4es, bedpans, crutches, stethoscope, thermometer	lntermediate level or low level disinfectant
Non- Critical environmental surfaces	Less direct contact with patient	Surfaces of medical equipment, examination table, computers	Low- level disinfectant

Sterilization of equipment in a hospital is carried out in CSSD. CSSD has been described in detail above. In this chapter, the disinfection/ sterilization of rest of the hospital items has been described

Properties of an ideal disinfectant (CDC):

- Broad spectrum : should have a wide antimicrobial spectrum
- Fast acting : should produce a rapid kill
- Not affected by environmental factors: should be active in the presence or organic matter (e.g., blood, sputum ,feces)
- Compatible with soaps, detergents, and other chemicals encountered in use
- Nontoxic: Should not be harmful to the user or patient
- Surface compatibility: Should not corrode instruments and metallic surfaces and should not cause the deterioration of cloth, rubber, plastics, and other materials
- Residual effect on treated surfaces : Should leave an antimicrobial film on the treated surface
- Easy to use with clear label directions
- Odorless : should have a pleasant odor or no odor to facilitate its routine use
- Economical : Should not be prohibitively high in cost
- Solubility: Should be stable in concentrate and use-dilution
- Cleaner : Should have good cleaning properties
- Environmentally friendly : Should not damage the environment on disposal

Table: Efficacy of disinfectants

Level of disinfectant	Bacterial spores	Tubercle bacilli	Nonenveloped viruses	Fungi	Enveloped Viruses	Vegetative bacteria
Low level disinfectant	No	No	No	+/-	Yes	Yes
Intermediate level disinfectant	No	Yes	Yes	Yes	Yes	Yes
High level disinfectant	May be	Yes	Yes	Yes	Yes	Yes
Chemical sterilant	Yes	Yes	Yes	Yes	Yes	Yes

The decreasing order of resistance of microorganisms to disinfectant or sterilizing agents is as follows-

Prions (higher resistance)> Bacterial spores > Cryptosporidium oocysts> Mycobacteria>> small non-enveloped viruses (polio)>Fungi >vegetative bacteria>Enveloped/medium to large size viruses (HIV,HBV,herpes)

Table – Common disinfectants and their spectrum of action

Germidicide & their concertratrions	Level of disinfectant	Bacteria &enveloped viruses	Fungi	Un-enveloped viruses	M.tuberculosis	Spore	Inactivated by organic matterc
Glutaraldehyde(2%)	High/CS	+	+	+	+	+	-
Formaldehyde (3-8%)	High/CS	+	+	+	+	+	-
H_2O_2(3- 25%)	High/CS	+	+	+	+	+	+/-
Chlorine (100-1000 ppm of free chlorine	Intermidiate	+	+	+	+	+/-	+
Isopropyl alcohol (60-95%)	Intermediate	+	+	+/-	+	-	+/-
Phenol (0.4-5%)	Intermediate	+	+	+/-	+	-	-
Iodopohore (30-50ppm of free iodine)	Intermediate	+	+	+	+/-	-	+
Quaternary ammonium compounds (0.4-1.6%)	Low	+	+/-	-	-	-	+

CS – Chemical Sterilant, + effectively kills, - Unable to kill, +/- variably kills, ppm-parts per million.

Disinfectants:

- **Glutaraldehyde**:

  Rapid acting -can be used up to 14 days after activation
  Long acting - can be used up to 28 days after activating
  Contact time- for disinfection 15-30 minutes
  - for sterilization 8-10 hours

- **Sterilium :**

  Contains 2-propanol,1-propanol ,macetronium ethyl sulfate
  Contact time for patient care hand wash: 1.5ml for 30 seconds.
  Contact time for surgical hand wash: 9 ml for 3minutes

- **Ecoshield:**

Contains stabilized hydrogen peroxide 11% w/v with 0.01% w/v diluted silver nitrate solution.
For surface disinfection: 10% v/v solution in de-ionized water with contact time of 60 minutes.

For fumigation: 1 litre of 20% v/v solution /1000 cu ft of space in 60 min.

- **Bacillocid:**
  Contains chemically bound formaldehyde, glutaraldehyde and benzalkonium chloride.
  Used as surface disinfectant at 2% solution in operation theatres and at 0.5% in wards and
  dressing rooms. Can be sprayed onto wet surfaces with a low pressure sprayer and allowed to dry
  slowly

- **Betadine**
  Iodophor .This is a high level disinfectant. Used for surgical hand scrub, skin disinfection.

- **Sodium Hypochlorite 10% stock-** Used for containing blood spills, disinfecting counter tops and other hard surfaces at 1 %. Used in laboratory for decontamination of waste from equipment as well as glassware at 5%.

1. **Alcohol -70%**
   Used for disinfection of non-disposable patient care items in out- patient departments and also in laboratory for cleaning of microscope lenses and surfaces of critical work surfaces.

DISINFECTANT PRODUCTS USED IN SVIMS

Stable bleaching powder

Characteristic	Specifications
Available chlorine	34.0%
Moisture	0.3%
Stability	1/15 mad

LIZOL

- **C**omposition: Benzalkonium chloride solution (80%) and 2.5 % w/w deionised water, Lauryl alcohol ethoxylate.

- Use:

  - Floor and bathroom surface: use one capful in half a bucket of water (4 liters). Gently mop the surface. No need to rinse

- This also used to clean the high touch areas.
- Kitchen: Use undiluted. Apply on dirty area and leave for ten minutes and rinse

- Safe for all surfaces: ceramic, marble, granite, mosaic.

List of high touch items:		
• BED (includes bed control buttons and cords • Bed rails • Bedside table, top and drawers, inside and out • BP cuff • Chair • Closet handles and inside closet • Door handles, all in the room	• Glucometer • Hand rail next to toilet • Hand rails • Headwall, all switches • IV pole • IV pump ledges that hold supplies • Light cord • Light switch • Oxygen flow meter • Patient privacy curtain	• Pulse oximeters • Sink including handles soap dispensers • Suction regulator • Telephone and cord • Trash cans • TV remote • Ventilators • Wall areas around toilet • Wheelchair • Window blinds • Window sills

Chlorine solutions for disinfection :

Chlorine solutions for disinfection can be prepared from house hold bleach (sodium hypochlorite solution) and also from calcium hypochlorite powder and bleaching powder (lime of Chlorine)

Household bleach

The best compound for the preparation of chlorine solutions is household bleach (also known as Clorox, Eau-de-Javel).

General instruction while preparing hypochlorite

- Household bleach is a solution of sodium hypochlorite which generally contains 5% (50g/litre or 50000ppm) available chlorine (range from 5.25-6.15%)
- Note that : different products may contain different concentrations of available chlorine, the concentration should be checked before use
- House hold bleach preparations can lose some of their chlorine over time. Hence, use newly manufactured bleach if possible.

- If the bleach does not smell strongly of chlorine it may not be satisfactory for the purpose and should not be used.
- Thick bleach solutions should never be used for disinfection purposes (other than in toilet bowels as they contain potentially poisonous additives.
- When preparing chlorine solutions for use note that :
- Daily preparation : Chlorine solutions gradually lose strength, and freshly diluted solutions must therefore be prepared daily
- Clear water should be used because organic matter destroys chlorine
- 1:10 bleach solutions is caustic, avoid direct contact with skin and eyes.
- Bleach solutions give off chlorine. Prepare them in a well –ventilated area.
- Use plastic containers for mixing and storing bleach solutions as metal containers are corroded rapidly and also affect the bleach
- Sodium hypochlorite should be kept dark bottles/containers and lid should be covered, else will lose potency.

Two different dilutions of bleach are used for disinfection.

1:10 bleach solution	1:100 bleach solution
Contains 0.5% chlorine concentration	Contains 0.05% chlorine concentration
Used for :excreta, bodies, spills of blood/body fluids ,vehicles and tires	Used for : Surfaces, medical equipment, bedding reusable protective clothing before it is laundered
	This is also recommended for : . Rinsing gloves between contact with different patients (if new gloves are not available) . Rinsing gloves,aprons, boots before leaving a patient's room . Disinfecting contaminated waste before disposal

Tables for the preparations of chlorine solutions from various chlorine compounds is given below

Table: Preparation of Chlorine solution from Household Bleach (liquid ,5%)

Household Bleach Solution	Dilution	Preparation	Chlorine (ppm)
Neat (5%) (Range- 5.25-6.15%)	None		50,000
0.5 % of sodium hypochlorite	1:10	1 volume of neat + 9 volumes of cold tap clean water	5000
0.05 % of sodium hypochlorite	1:100	1 volume of neat +9 9 volumes of cold tap	500

		clean water	
1% of sodium hypochlorite	1:5	1 volume of neat +4 volumes of cold tap clean water	10,000
0.1% of sodium hypochlorite	1:50	1 volume of neat +49 volumes of cold tap clean water	1000

Table: Disinfection procedure for individual items or equipment and in between patients

(Adapted from CDC, Damani's Manual of infection prevention and control and Local policy, SVIMS)

Items	Procedure	Comments
Airways	Clean with soap and water and gas (EtO) sterilization (CSSD) or use disposable	
Ampoules/vials	Wipe neck or rubber top with 70% isopropyl alcohol and allow drying before opening or piercing. Do not immerse ampoules/vials in disinfectant solution	
Auroscope tip	Use single – use disposable tips If reusable tips are used then send to CSSD for sterilization. Chemical disinfectant should be used only when other methods are unavailable.	
Oxygen – masks	Clean with soap and water send to (ETO)	
Ambubag	Should be cleaned with detergent and water, dried and sterilized (ETO)	
Arterial catheters	Sterile, single use only, must be discarded after use.	
Baby equipment feeding bottles & teats PALADAL to be used for baby feeding	Not recommended Autoclaving	
Baby weighing scales A fresh liner should be used (or) baby towel for each baby.	Clean tray as necessary with detergent and water.	If contaminated should be Wiped hypochlorite 1000 ppm after washing
Baths/showers/shower chairs	Not recommended	
Baby bath	Separate basins for each baby	

Beds and couches Frame (or) sofa	Refer to housekeeping section	If contaminated with body fluids, See spillage management policy. If used in isolation room after cleaning, should be wiped with a disinfectant Colonizes/ infection patients. After cleaning with detergent, disinfect with hypochlorite 1000 ppm solution
Bowls (surgical)	Primary wash and Return to CSSD	
Bowls (Washing)	Wash with detergent and water and decontaminate with 1 % hypochlorite solution/bleaching solution, rinse and dry after each use. Store inverted and separated	
Mattresses and pillows should be covered with rexine sheet 6 months check for durability	Refer housekeeping section	If contaminated with body fluids, the blood spills management policy should be implemented. Should not be used if cover is damaged. Contaminated pillows must be discarded. Torn mattress covers must be replaced before mattress is re-used
Bedpans and urinals	Refer housekeeping section	Bedpan holders, and storage racks/shelves must be cleaned with detergents on a daily basis.
Buckets	Refer housekeeping section	
Breast pumps	For single patient use- should be washed with detergent and water, immersed in sodium hypochlorite 125ppm available cl_2 for 30 min, freshly made up from tablets according to manufacturer's instructions	Heat sterilize before use by subsequent patients
Brushes Nail Toilet	Refer housekeeping section	
Cardiac and urinary catheters, IV devices, and all other invasive devices. i.e.	Use sterile single- use disposable item only. If reuse according to the local policy	

needles, syringes		
Cardiac monitors, defibrillators, and ECG	Use single – use disposable ECG pads. Clean and disinfect ECG leads and machine with 70 % alcohol	
Carpets	Refer to housekeeping section	Should be shampooed or steam cleaned in isolation rooms as part of terminal cleans
Commodes	Refer to housekeeping section	If soiled or used in isolation, should be wiped with sodium hypochlorite 2% and dried, after cleaning
Cheatle forceps	Do not use. If used autoclave daily and stored in sterile container use separate dressing packs for dressing	
Cleaning equipment	Refer to housekeeping section	
Couches (examination)	Refer to housekeeping section	
Cots	Refer to housekeeping section	
Cradles	Refer to housekeeping section	
Crockery and cutlery (spoons and utensils	Should be heat disinfected in dishwasher. If washed in sink, with water and detergent	
Curtains	Refer to housekeeping section	
Curtains (between patients)	Refer to housekeeping section	
Drainage bottles	1.Disposable – Single use 2. Reusable – rinse and return to CSSD	Wash with detergent and water; put jars in the disinfectant solution. Leave for contact time, rinse and store dry, or send to CSSD.Weekly autoclaving or HLD is highly recommended
Drip stands Urobag bag stands	Refer to housekeeping section	
Ear Pieces for auroscope and after use in isolation	Should be cleaned with detergent and water and dried	To be returned to CSSD after use in isolation
ECG leads and machines	Wash with detergent and water, then 70% alcohol wipe.	
Leads and monitors	Should be dismantled to smallest components and cleaned with detergent and water and dried	
Endoscopes- invasive	Refer endoscope treatment	

	policy	
Endoscopes- non-invasive	Refer endoscope treatment policy	
Endotracheal tubes	Single use only	
Eye protection	Should be cleaned with detergent and water and dried.	For blood splashes blood spillage policy should be followed
Fixtures, fittings and ledges	Refer to housekeeping section	
Floors	Refer to housekeeping section	For blood splashes blood spillage policy should be followed
Furniture	Refer to housekeeping section	
Haemodialysis machines	Thoroughly clean between patients and disinfect at the end of the day per manufacturer's recommendations Colonized patients: after cleaning with detergent, disinfect with hypochlorite (1000 ppm available Cl_2) solution or other appropriate disinfectant as per manufacturer's recommendations.	
Hoist/sling	Refer to housekeeping section	
Humidifiers	Should be cleaned and sterilized at low temperature. (ETO).	Drain at least once each day, clean with detergent and water Refill with sterile water and label the humidifiers or follow Manufacturer's instructions. Humidifiers which are not in use should be cleaned and kept dry.
Infant Incubators	Should be cleaned with detergent and water and switch on to dry.	Terminal sterilization with ethylene oxide gas may be required after some infections.
Infant incubators	Routinely wash with detergent and dry with disposable wipe in a daily basis. Colonized/infected patients: after cleaning, wipe with 70% isopropyl alcohol impregnated wipe or use hypochlorite (125	

	ppm available Cl_2) solution or other disinfectant as per manufacturer's recommendation and allow to dry. The cleaning and disinfection should be done in a separate area.	
Intravenous monitoring pumps (And feed pumps)	Should be cleaned with detergent and water and dried.	After use in isolation wipe with sodium hypochlorite 2% and dry, after cleaning
Instruments	After single use to be returned to CSSD	
Linen	Refer to laundry section	
Laryngoscope	Decontaminate with 0.5% bleaching solution if blood stained. Clean with detergent and water and HLD is done with glutaraldehyde 2%. Bulb of the laryngoscope should be removed and cleaning with spirit swab.	
Locker Tops	Damp dust daily with detergent solution and allow drying. Colonized/infected patients: after cleaning with detergent, disinfect with hypochlorite 1000 ppm available Cl_2 solution or other appropriate disinfectant and allow to dry.	
Medicine trays	To be cleaned with detergent and water weekly	If blood spillage seen blood spillage policy
Peak flow	Disposable single patient use.	
Proctoscope	Disposable – single use. Reusable to be rinsed in hypochlorite and returned to CSSD	
Nebulizers	Cleaning and low temperature sterilization (ETO) between patients. Fill with sterile water only.	Send for cleaning reprocessing to CSSD
Nebulizer tubing	Wash with detergent and water and send to CSSD (ETO)	
Pressure relieving devices	Should be cleaned with detergents and water and dried	
Razors hair removal for OT preparation	Refer housekeeping section	

Scissors	Surface disinfect with a 70% alcohol impregnated wipe before use. If visibly soiled clean first with a detergent solution for sterile use (high level disinfection	
Shaving brush	Should not be used unless supplied by the patients for their own use. Rinse under running water and stored dry.	
Skin disinfection	Should be preferred to bath or bed baths	
Soap dispensers	Should be cleaned weekly with detergent and water and dried.	
Sphygmo-manometer cuffs	Use dedicated items in high – risk areas (g.ICU) or patients known to be colonized/ infected. Wash sleeve with soap and water once a week In between patients Disinfect with 70% alcohol impregnated wipe to clean tubing and inflation bladder.	After use in isolation, should be laundered in washing machine
Spillages	Refer to spillage management policy	
Splints and walking frames	Wash and clean with detergent and allow to dry.	
Sputum pots	Surface disinfect with 70% alcohol impregnated wipe between patients. Use dedicated stethoscope in high –risk area e.g. ICU.NNU or patients with infection or colonized with MDROs.	
Suction bottles	Disposal lines. Must have scaled when 75% full and placed in yellow plastic bag.. Re-usable (jar and tubings), should be cleaned with 1% sodium hypochlorite and dried. Must be changed daily and in between each patient. To be stored dry when both in use.	At least weekly autoclaving of suction jars should be done, wherever applicable. Minimum 1-2% sodium hypochlorite solution should be kept in jar in volume which is 1/10 volume of the jar. After use, add equal quantity of hypochlorite for equal quantity of hypochlorite

		for disinfection at source before discarding the content.
Surgical instruments	Transport safely in a closed rigid container to CSSD for sterilization. Clean manually or use thermal washer – disinfector and then steam sterilize all instruments in CSSD	
Surgical instruments	Steam sterilize if heat tolerant. Single use items may be used.	
Thermometers	Oral: Single – patient use thermometers must be dedicated for infection patients and patient in high –risk areas, e.g.ICU. They should be cleaned and wiped with a 70% isopropyl alcohol impregnated wipe after each use and stored dry. On discharge of patient ,wash both thermometer and thermometer holder with detergent, immerse in 70 % alcohol for 10min.Wipe and store dry Communal thermometers: Wipe clean, wash in a cold neutral detergent, rinse, dry and immerse in 70% isopropyl alcohol for 10 min Wipe and store dry. Rectal : Clean and wash in detergent solution after each use, wipe dry and immerse in 70 % alcohol for 10 min. Wipe and store dry Electronic: Where possible use a single- use sleeve. If not possible, use either single –use thermometer or clean and disinfect between use. Do not use without sleeve or on patients with an infectious disease. Single – Use sleeve, Single-patient use on high-risk areas or infected patient. Clean, then wipe with a 70 % isopropyl	

	alcohol impregnated wipe after each use. Tympanic: Single – use sleeve.	
Telephones	To be wiped with 70 % alcohol	
Toilet seats	Refer housekeeping section	
Toilet seats and	Refer housekeeping section	
Toilet seats	Refer housekeeping section	
Tonometer prisms (Applicators)	Immersion in 0.05% hypochlorite (500 parts per million available chlorine) for 10 minutes	A fresh solution should be prepared at the start of each clinic.
Toys	Soft toys: Avoid use of soft toys Hard toys : wash with detergent and disinfect with alcohol impregnated wipe or use hypochlorite (1000 ppm av Cl_2 solution For children with infection diseases do not use communal toys or those which cannot be easily disinfected	
Trolleys (Dressing)	Clean and wipe trolley top with a 70% isopropyl alcohol impregnated wipe before use. If contaminated, clean with detergent and then disinfect with a 70 % isopropyl alcohol impregnated wipe and dry.	
Ultra sound machine	Damp dust with detergent solution and allows surface to dry before use. Draw up local protocol for cleaning and disinfection based on the manufacture's recommendations.	
Vaginal speculae	After use immerse in hypochlorite for 15-30 min and send to CSSD for sterilization or use single-use	
Ventilator and Breathing circuits	Use single- use or heat disinfect/sterilize in CSSD. Infected patients: for Patient with respiratory infection and other serious infection use disposable tubing. Never use glutaraldehyde to	

	disinfect respiratory equipment.	
Ventilators	After every patient, clean and disinfect ventilators. Dismantle and sterilize/disinfect (high-level) all re-useable components as per the manufacture's recommendations	
Ventilators	Daily cleaning and disinfection of tubing must be done. After 72 hrs of use autoclaving should be done for autoclavable tubings. Humidifier water must be changed at least every 8 hrs. Daily autoclaving of humidifiers is recommended where autoclavable.	After removing of ventilator tubes wash it with detergent and water and send to CSSD for autoclaving
Vomit bowls	Contents must be emptied into sluice then rinsed and washed and disinfected with hot water and detergent and dried.	
Walls	Refer housekeeping section	
Wash bowls	Patients must have own dedicated bowl. After each patient's use, should be cleaned with detergent.	
Wheel chairs	Patients own – Should be cleaned with detergent and water as necessary. Hospital- clean between patients with detergent and water, rinse and dry.	
Medicine Trolleys Wash at least weekly with hot soapy water. Ensure spillages are cleaned promptly		

STERILIZATION

Sterilization is defined as a process where all microbes are removed from a defined object, inclusive of bacterial endospores**.**

i. STEAM

Autoclaves (gravity displacement) are used in CSSD for instruments, certain plastics linen gauze and other items. Flash sterilization is used for OT in emergency situations.

Decontamination autoclave is available separately for laboratory glassware.

ii. ALDEHYDE

Glutaraldehyde may be used in places like the endoscopy unit, cardiac catheterization labs.

For steam and gas methods, chemical as well as microbiological indicators are used to check the effectiveness of sterilization.

Microbiological indicators are used once a week: namely spores of *Bacillus stearothermophilus* for steam sterilizers and *Bacillus subtilis* for ethylene oxide. Vials are removed from sterilizers and sent to microbiology laboratory where they are incubated at relevant temperatures for 48 hours. Report is sent to CSSD.
An expiry date is given for sterile articles based on the packing material used.

iii. FUMIGATION:

- Eco-shield is used for fumigation using Fog spraying machine.
- Operation theatres are fumigated once a week and if necessary such as in case of a septic wound being drained.
- Other patient care areas are not regularly fumigated and not recommended.
- Decision as to necessity is taken by in charge of concerned patient care area.

Recommended Practice Guidelines for All Types of Steam Sterilizers

Device Preparation

Devices should be prepared for sterilization in the following manner:

a) Clean, and remove excess water.

b) Jointed instruments should be in the open or unlocked position.

c) Multipiece or sliding pieces should be disassembled unless otherwise indicated by the device manufacturer.

d) Devices with concave surfaces that retain water should be placed in a manner such that condensate does not collect.
e) Instruments with lumens should be moistened with distilled water immediately prior to sterilization.
f) Heavy items should be arranged so as to not damage lighter more delicate items.
g) Sharp instruments should have tips protected.

Fogging (Fumigation)

- This method of disinfection is used after discharge of a patient with communicable diseases or before admitting a patient after high risk operation.
- Action time 45 minutes to 1 hr.
- Mode of use:11% Hydrogen Peroxide+0.01 Silver Nitrate(Ecosheild) in water(800 ml water and 200 ml solution)
- Room should be kept closed for two hours.

d. Documented policy and procedure for reprocessing of devices which are meant for re-use :

Sterilization is the elimination of all disease-producing microorganisms, including bacterial spores (e.g. Clostridium and Bacillus species). Prions are not susceptible to routine sterilization. Sterilization is used on critical medical devices and, whenever possible, semi-critical medical devices.

Most medical and surgical devices used in health-care facilities are made of materials that are heat stable and therefore undergo heat, primarily steam, sterilization. For heat-sensitive devices that cannot withstand steam sterilization, some examples of chemical sterilants available are:

a) ETO gas
b) Hydrogen peroxide gas
c) Hydrogen peroxide gas plasma
d) Formaldehyde gas
e) Ozone
f) Dry heat

Choosing the correct sterilization process is important so as not to cause damage to the item or compromise sterility. Sterilization and the provision of a sterile device for a patient procedure is dependent on the whole cycle of decontamination, including cleaning, packaging,

sterilization, storage/transport, and even to the point of preparing and using the device on a patient.

STERILIZATION PROCESS

Risk assessment as discussed in Section 1 applies here.

In summary: ñ

Medical devices that have contact with sterile body tissues or fluids are considered critical items. All critical medical devices shall be cleaned and then sterilized because microbial contamination could result in disease transmission

Critical items (i.e. those that will enter a sterile body cavity) include, but are not limited to, surgical instruments, implants, foot care equipment, endoscopes that enter sterile cavities and spaces, colposcopy equipment, biopsy forceps and brushes, eye and dental instruments

Whenever possible, semi-critical medical devices should be sterilized. (Semi-critical medical devices are in contact with non-intact skin or mucous membranes, but do not penetrate them.)

Device compatibility For a medical device to be deemed compatible with a particular sterilization method, it must be able to be effectively sterilized and at the same time remain functional following sterilization. Among other considerations, the ability of the sterilization system to effectively sterilize the medical device will depend on component materials and device design, as well as the level of bio-burden (cleanliness) prior to sterilization.

Functionality is the ability of a medical device to withstand the sterilization process and to remain within operating specifications. The device manufacturer will test its functionality after processing through repeated sterilization cycles.

STEAM STERILIZATION

Steam sterilization is a process that uses saturated steam under pressure as the sterilant. It is the preferred method for sterilizing critical medical devices. The removal of air is essential to ensure an efficient sterilization process – sterilization cannot occur in the presence of air.

Types of steam sterilizers

There are several types of steam sterilizers that utilize different methods to remove air from packages and the chamber, such as dynamic air removal (e.g. prevacuum) and steam-flush pressure-pulse sterilizers, or passive air removal (e.g. gravity).

Prevacuum sterilizers

Use a vacuum pump or water ejector to remove air from the chamber and packaged devices during the preconditioning phase and prior to sterilization.

Operate at 132ÆC to 135ÆC Steam-flush pressure-pulse

Use a repeated sequence of a steam flush and pressure pulse to remove air from the chamber and packaged items

Operate at 121ÆC to 123ÆC, 132ÆC to 135ÆC, or 141ÆC to 144ÆC Gravity sterilizers ñ Gravity is used to displace the air from the sterilizer chamber and packaged devices

Operate at 121ÆC or higher Steam sterilizers vary in chamber size from small table top models to large floor-loading models.

The recommended practices described in this document apply to all types and sizes of steam sterilizers, including table top sterilizers. Written, validated, device-specific instructions from the device manufacturer and sterilizer efficacy testing from the sterilizer manufacturer must be obtained when utilizing any sterilization method.

Steam sterilization methods

The following types of loads/cycles have been developed and tested by steam sterilization manufacturers:

Wrapped devices (non-porous cycles)

Textile packs (porous cycles).

Porous refers to the ability to trap air/liquid within the lumen, channel or hollow devices (e.g. dental hand pieces and rigid scopes may require special cycle conditions, depending on the length and diameter of the lumen)

Utensils and glassware

Combination of porous and non-porous loads

Liquids and solutions ñ Immediate use steam sterilization (IUSS)

Porous and non-porous cycles/loads

Steam sterilization is achieved via direct contact of the steam with all surfaces of the medical device(s)

Direct contact can only be achieved after all air has been removed from the devices, the packages and the chamber

Non-porous items, such as stainless steel forceps, needle holders, scissors, and retractors, do not trap air and thus allow surface contact to be readily achieved

Porous items, such as textiles, wrappers, paper, rubber or plastic items, items with lumens or with sliding parts that can trap air/liquid and/or present a challenge to surface contact by the sterilant, require longer exposure times to ensure adequate steam penetration. Porous loads are often a challenge to sterilize by steam

Longer cycle times for porous items are particularly important for sterilizers that rely on gravity displacement to remove air

In all instances, users must follow, monitor and record the sterilization time and temperature requirements specified by the manufacturer when sterilizing non-porous and porous medical devices

Immediate use system sterilization (IUSS) / "flash" sterilization:

IUSS or "flash" sterilization is a common term that describes the practice of fast sterilization of non-porous and/or non-cannulated surgical instruments in an unwrapped condition in downward displacement steam instrument sterilizers located close to the point where the instruments will be used immediately. In the past, IUSS was the predominant way of providing sterile instruments for surgery. Special high-speed sterilizers are usually located in the operating room in order to process unwrapped instruments and instruments for extremely urgent use. For example, the only available hand piece is dropped on the floor in the middle of the procedure and this single instrument needs to be sterilized in a hurry. These sterilizers operate at 134^{o}C for 3-10 minutes. IUSS delivers the instruments wet and very hot into the operating room environment

Indications for the use of IUSS If a IUSS sterilizer must be used, it should be used only after all of the following conditions have been met:

Work practices should ensure proper cleaning, inspection, and arrangement of instruments before sterilization

Physical layout of the area ensures direct delivery of sterilized items to the point of use

Procedures are developed, followed and audited to ensure aseptic handling and staff safety during transfer of the sterilized items from the sterilizer to the point of use

Items are needed for use immediately following IUSS and as soon as the device cools so as not to burn the patient IUSS versus pre-pack.

The alternative approach to IUSS is to provide instruments in a wrapped, dry and cool condition (temperature depending on the time since steam sterilization). This is possible when there is a sufficient inventory of instruments and equipment to allow for a "turnaround" time for reprocessing (such as pre-vacuum sterilizers with fast cycles) in a well-appointed and staffed SSD. In smaller surgical facilities, SSD activities often occur in the operating room area. However, this represents a compromise of several desirable standards of control of particulate and microbial contamination in the area where sterile packs are being produced.

There is now a strong movement towards the routine preparation of sterile instruments in a wrapped, dry and cool condition for use in the operating room for the following reasons:

Immediate advantages to case-by-case organization of sterile instruments by operating theatre staff

The typical operating theatre is not designed or equipped to clean instruments as reliably and consistently as a properly appointed SSD and there are concerns regarding the adequacy of cleaning and drying of instruments in the operating theatre prior to using IUSS processing

Sterility of sets of instruments can be uncertain following the use of sterilizers designed and intended only for single dropped instruments; they should not be used for routine sterilization of instrument sets

The sterilizer may not be located in an area immediately adjacent to the operating theatre; thus, the delivery of IUSS-sterilized devices to their point of use compromises their sterility ñ Patient injury has occurred from IUSS-sterilized items, including full thickness burns resulting in permanent scars, P. aeruginosa meningitis from IUSS-sterilized implantable devices and surgical site infection. A compromise is the commercially-available method of delivery of IUSS-sterilized devices in an enclosed container with valves that automatically close at the end of steam sterilization (FLASH-PAKì)33. Manufacturer's recommendations should be observed in relation to the minimum temperature exposure time. Inspection and maintenance of such systems should be carried out on a regular basis as recommended by the manufacturer.

IUSS recommendations

Restrict use to emergencies, such as unexpected surgery, or dropped instruments

In most emergency situations, the risk/benefit ratio is low enough to justify the use of IUSS-sterilized objects

In non-emergency situations, the risk/benefit ratio is higher, particularly when implantable devices are involved

IUSS sterilizers must never be used for implants, suction tubing or cannulars or any other product not specifically validated for the IUSS process. Minimizing IUSS sterilization The following points should be considered for action to minimize routine IUSS sterilization:

Increase the available inventory of certain instruments, particularly rigid endoscopes

Replace older devices with newer ones designed for steam sterilization

Provide more instrument sets in wrapped form, focusing on the advantages this provides both during surgery and for the management of the operating theatre

Ensure the appropriate design of the SSD or sterile processing area to optimize the production and timely delivery of wrapped instrument packs

Manage operating theatre case lists in a way that optimizes use of the available instruments in association with their sterile processing requirements

TABLE TOP STERILIZERS: The table top model is the most frequently used steam sterilizer in outpatient, dental and rural clinics. They are defined as a sterilizer that has a chamber volume of not more than two cubic feet, which generates its own steam when distilled or deionized water is added by the user. These sterilizers are designed for small instruments, such as dental instruments, and not recommended for any lumen instruments. The ability of the sterilizer to reach the physical parameters necessary to achieve sterilization should be monitored by mechanical, chemical and biological indicators. Ensure that items or packs

removed from the sterilizer are visibly dry as moisture will wick contaminants into the package contents. Unwrapped items are vulnerable to contamination.

These “pot-style” sterilizers look and operate just like a pressure cooker. Distilled or deionized water is poured into the bottom to the required level. Clean, unwrapped instruments are placed in the basket, lowered into the sterilizer and placed on a support that keeps the basket above the water reservoir. The sterilizer is then sealed and turned on. As with other types of tabletop sterilizers, the water is boiled into steam, forcing out air until the sterilizer valve closes. Pressure is increased until the desired temperature and pressure are achieved. This process usually takes less than 5 minutes. The complete sterilizer cycle lasts approximately 16 minutes, with an additional 10 minutes for the pressure to drop to normal, after which the lid can be opened.

TABLETOP STERILIZERS WITH A CASSETTE CHAMBER: Some steam sterilizers have a reusable cassette that is, in effect, the chamber. The cassette is a metal container that may vary in size, depending on the size of the sterilizer. It consists of a tray, lid and some form of gasket to seal the unit. In the base of the cassette, there are two apertures that allow for the movement of steam and air through the cassette; one is an inlet and the other is an exit. Always make sure that these openings are clean and free from obstruction. A quantity of instruments (which may be wrapped if desired) is placed in the cassette, which is then closed and put into the sterilizer. Wrapped instruments take about 14 minutes to be sterilized and dried; unwrapped instruments will take less time.

A drying cycle is an optional feature and, therefore, devices come out wet after being processed and are not acceptable for use on a patient. Be aware that unwrapped instruments will not remain sterile once they have been removed from the sterilizer. The instruments must be handled carefully to minimize contamination. As with all equipment, follow the manufacturer’s instructions for use, e.g. certain devices could be sensitive to contaminants in the water, hence the manufacturer’s recommendation to use only distilled water in the reservoir.

Loading a tabletop sterilizer During sterilization, the steam must circulate freely around each pack and have the unrestricted ability to penetrate into and exit from each pack. Paper/plastic packages, linen packs, and any packs with a solid bottom must be placed on their sides. This will ensure air removal, contact with steam and allow any condensation to be drained. When placed side-by-side, paper/plastic packages must be placed with the plastic side facing the paper side of the next package. Air and steam only pass through the paper side of a paper/plastic package.

No package should come into contact with the chamber wall as this contact promotes staining and will damage the package; the free circulation of steam will be also significantly impaired.

If the user intends to sterilize other products, apart from a hard-surfaced device, e.g. a liquid, the manufacturer should be contacted to confirm if the sterilizer supports this use, and if so, how to do it. Normal cycles and techniques cannot be used for this application.

Unloading a table top sterilizer Do not handle sterile packages until they are cool. When touched, hot packages act as wicks for moisture, which destroys the barrier quality of the package. The microorganisms from your hands could then easily contaminate the package. Check the available indicators to make sure that the essential requirements for sterilization have been achieved. Carefully inspect the packs for wetness; if wet, the package must be reprocessed. Warm packs must not be placed on cool surfaces (e.g. metal counters) or near drafts (e.g. air vents). This will cause condensation to form that could contaminate the contents. Any sterilized item that becomes wet or is dropped, torn, compressed or otherwise mishandled should be considered contaminated and must be reprocessed.

Reprocessing of devices which are meant for re-use :

Auroscope tip	Use single – use disposable tips If reusable tips are used then send to CSSD for sterilization. Chemical disinfectant should be used only when other methods are unavailable.	
Ambubag	Should be cleaned with detergent and water, dried and sterilized (ETO)	
Baby weighing scales A fresh liner should be used (or) baby towel for each baby.	Clean tray as necessary with detergent and water.	If contaminated should be Wiped hypochlorite 1000 ppm after washing
Bowls (surgical)	Primary wash and Return to CSSD	
Bowls (Washing)	Wash with detergent and water and decontaminate with 1 % hypochlorite solution/bleaching solution, rinse and dry after each use. Store inverted and separated	
Mattresses and pillows should be covered with rexine sheet 6 months check for durability	Refer housekeeping section	If contaminated with body fluids, the blood spills management policy should be implemented. Should not be used if cover is damaged. Contaminated

		pillows must be discarded. Torn mattress covers must be replaced before mattress is re-used
Bedpans and urinals	Refer housekeeping section	Bedpan holders, and storage racks/shelves must be cleaned with detergents on a daily basis.
Buckets	Refer housekeeping section	
Breast pumps	For single patient use- should be washed with detergent and water, immersed in sodium hypochlorite 125ppm available cl_2 for 30 min, freshly made up from tablets according to manufacturer's instructions	Heat sterilize before use by subsequent patients
Cardiac and urinary catheters, IV devices, and all other invasive devices. i.e. needles, syringes	Use sterile single- use disposable item only. If reuse according to the local policy	
Cardiac monitors, defibrillators, and ECG	Use single – use disposable ECG pads. Clean and disinfect ECG leads and machine with 70 % alcohol	
Drainage bottles	1.Disposable – Single use 2. Reusable – rinse and return to CSSD	Wash with detergent and water; put jars in the disinfectant solution. Leave for contact time, rinse and store dry, or send to CSSD.Weekly autoclaving or HLD is highly recommended
Ear Pieces for auroscope and after use in isolation	Should be cleaned with detergent and water and dried	To be returned to CSSD after use in isolation
ECG leads and machines	Wash with detergent and water, then 70% alcohol wipe.	
Leads and monitors	Should be dismantled to smallest components and cleaned with detergent and water and dried	
Endoscopes- invasive	Refer endoscope treatment policy	
Endoscopes- non-invasive	Refer endoscope treatment policy	
Endotracheal tubes	Single use only	
Haemodialysis machines	Thoroughly clean between	

	patients and disinfect at the end of the day per manufacturer's recommendations Colonized patients: after cleaning with detergent, disinfect with hypochlorite (1000 ppm available Cl_2) solution or other appropriate disinfectant as per manufacturer's recommendations.	
Humidifiers	Should be cleaned and sterilized at low temperature. (ETO).	Drain at least once each day, clean with detergent and water Refill with sterile water and label the humidifiers or follow Manufacturer's instructions. Humidifiers which are not in use should be cleaned and kept dry.
Infant Incubators	Should be cleaned with detergent and water and switch on to dry.	Terminal sterilization with ethylene oxide gas may be required after some infections.
Infant incubators	Routinely wash with detergent and dry with disposable wipe in a daily basis. Colonized/infected patients: after cleaning, wipe with 70% isopropyl alcohol impregnated wipe or use hypochlorite (125 ppm available Cl_2) solution or other disinfectant as per manufacturer's recommendation and allow to dry. The cleaning and disinfection should be done in a separate area.	
Intravenous monitoring pumps (And feed pumps)	Should be cleaned with detergent and water and dried.	After use in isolation wipe with sodium hypochlorite 2% and dry, after cleaning
Instruments	After single use to be returned to CSSD	
Linen	Refer to laundry section	
Laryngoscope	Decontaminate with 0.5% bleaching solution if blood stained. Clean with detergent	

	and water and HLD is done with glutaraldehyde 2%. Bulb of the laryngoscope should be removed and cleaning with spirit swab.	
Proctoscope	Disposable – single use. Reusable to be rinsed in hypochlorite and returned to CSSD	
Nebulizers	Cleaning and low temperature sterilization (ETO) between patients. Fill with sterile water only.	Send for cleaning reprocessing to CSSD
Nebulizer tubing	Wash with detergent and water and send to CSSD (ETO)	
Pressure relieving devices	Should be cleaned with detergents and water and dried	
Razors hair removal for OT preparation	Refer housekeeping section	
Scissors	Surface disinfect with a 70% alcohol impregnated wipe before use. If visibly soiled clean first with a detergent solution for sterile use (high level disinfection	
Shaving brush	Should not be used unless supplied by the patients for their own use. Rinse under running water and stored dry.	
Sphygmo-manometer cuffs	Use dedicated items in high – risk areas (g.ICU) or patients known to be colonized/ infected. Wash sleeve with soap and water once a week In between patients Disinfect with 70% alcohol impregnated wipe to clean tubing and inflation bladder.	After use in isolation, should be laundered in washing machine
Splints and walking frames	Wash and clean with detergent and allow to dry.	
Suction bottles	Disposal lines. Must have scaled when 75% full and placed in yellow plastic bag.. Re-usable (jar and tubings), should be cleaned with 1%	At least weekly autoclaving of suction jars should be done, wherever applicable. Minimum 1-2% sodium hypochlorite solution should

	sodium hypochlorite and dried. Must be changed daily and in between each patient. To be stored dry when both in use.	be kept in jar in volume which is 1/10 volume of the jar. After use, add equal quantity of hypochlorite for equal quantity of hypochlorite for disinfection at source before discarding the content.
Surgical instruments	Transport safely in a closed rigid container to CSSD for sterilization. Clean manually or use thermal washer – disinfector and then steam sterilize all instruments in CSSD	
Surgical instruments	Steam sterilize if heat tolerant. Single use items may be used.	
Thermometers	Oral: Single – patient use thermometers must be dedicated for infection patients and patient in high – risk areas, e.g.ICU. They should be cleaned and wiped with a 70% isopropyl alcohol impregnated wipe after each use and stored dry. On discharge of patient ,wash both thermometer and thermometer holder with detergent, immerse in 70 % alcohol for 10min.Wipe and store dry Communal thermometers: Wipe clean, wash in a cold neutral detergent, rinse, dry and immerse in 70% isopropyl alcohol for 10 min Wipe and store dry. Rectal : Clean and wash in detergent solution after each use, wipe dry and immerse in 70 % alcohol for 10 min. Wipe and store dry Electronic: Where possible use a single- use sleeve. If not possible, use either single –use thermometer or clean and	

	disinfect between use. Do not use without sleeve or on patients with an infectious disease. Single – Use sleeve, Single-patient use on high-risk areas or infected patient. Clean, then wipe with a 70 % isopropyl alcohol impregnated wipe after each use. Tympanic: Single – use sleeve.	
Telephones	To be wiped with 70 % alcohol	
Tonometer prisms (Applicators)	Immersion in 0.05% hypochlorite (500 parts per million available chlorine) for 10 minutes	A fresh solution should be prepared at the start of each clinic.
Trolleys (Dressing)	Clean and wipe trolley top with a 70% isopropyl alcohol impregnated wipe before use. If contaminated, clean with detergent and then disinfect with a 70 % isopropyl alcohol impregnated wipe and dry.	
Ultra sound machine	Damp dust with detergent solution and allows surface to dry before use. Draw up local protocol for cleaning and disinfection based on the manufacture's recommendations.	
Vaginal speculae	After use immerse in hypochlorite for 15-30 min and send to CSSD for sterilization or use single-use	
Ventilator and Breathing circuits	Use single- use or heat disinfect/sterilize in CSSD. Infected patients: for Patient with respiratory infection and other serious infection use disposable tubing. Never use glutaraldehyde to disinfect respiratory equipment.	
Ventilators	After every patient, clean and disinfect ventilators.	

	Dismantle and sterilize/disinfect (high-level) all re-useable components as per the manufacture's recommendations	
Ventilators	Daily cleaning and disinfection of tubing must be done. After 72 hrs of use autoclaving should be done for autoclavable tubings. Humidifier water must be changed at least every 8 hrs. Daily autoclaving of humidifiers is recommended where autoclavable.	After removing of ventilator tubes wash it with detergent and water and send to CSSD for autoclaving
Vomit bowls	Contents must be emptied into sluice then rinsed and washed and disinfected with hot water and detergent and dried.	
Wash bowls	Patients must have own dedicated bowl. After each patient's use, should be cleaned with detergent.	
Wheel chairs	Patients own – Should be cleaned with detergent and water as necessary. Hospital- clean between patients with detergent and water, rinse and dry.	
Medicine Trolleys Wash at least weekly with hot soapy water. Ensure spillages are cleaned promptly		

Endoscope Reprocessing:

Policy and Procedure

Endoscopes are considered semi-critical devices on the Spaulding Scale and require, at a minimum, high-level disinfection with a FDA approved disinfectant.

Personnel performing reprocessing of flexible endoscopes shall demonstrate competency in the care and reprocessing of endoscopes and related equipment. Personnel shall also demonstrate competency in infection control and safe use of chemicals

Appropriate personal protective equipment must be worn.

All endoscopes shall be pre-cleaned according to the manufacturer's guidelines immediately following the procedure.

After each use, all endoscopes shall be disassembled and leak tested according to manufacturer's instructions.

All endoscopes and accessories will be thoroughly and properly cleaned with an enzymatic detergent prior to high-level disinfection and/or sterilization. Manufacturer's instructions for preparation and use of the enzymatic detergent shall be followed. The prepared detergent shall be discarded after each use. Appropriately sized brushes will be used for cleaning. All endoscopes will be properly rinsed after cleaning according to manufacturer guidelines.

Reprocessing for each endoscope shall be performed according to the manufacturer's instructions specific to that endoscope. An EPA-registered disinfectant solution will be utilized for all endoscopes and compatible accessories for high level disinfection and/or sterilization. Manufacturer instructions shall be followed in the preparation, testing and use of the disinfectant solution. Manufacturer guidelines for exposure time and temperature will be followed. Each endoscope and it components shall be completely immersed in the disinfectant solution and all channels must be disinfected during reprocessing.

Following high-level disinfection, all endoscopes and accessories shall be rinsed and dried in accordance with manufacturer instructions.

When an automated processor is used in lieu of high-level disinfection, manufacturer's directions for processing shall be followed.

Disinfected and dried endoscopes shall be properly stored in a vertical position away from the reprocessing area in a location that will provide protection from contamination.

Reusable endoscopic accessories that break the mucosal barrier will be mechanically cleaned and sterilized after each patient use.

When a sterilizer is used, manufacturer's instructions for use shall be followed.When automated processors and/or sterilizers are used, maintenance and repair shall be performed according to manufacturer instructions and shall be documented.

Personnel shall routinely inspect endoscopes and all related equipment and supplies for integrity, function, and cleanliness. Damaged or soiled endoscopes or accessories shall not be used.

e. <u>Regualr validation tests for sterilization are*:</u>

- Physical
- Chemical and
- Biological indicators

Physical indicators:

These are the digital displays, gauge, record charts, printouts of the sterilizer equipment which verify the parameters of sterilization cycle are met or not such as temperature, time and pressure etc.

- They only monitor one point in the chamber.
- Collect the printouts and properly record it.

Chemical indicators:

Chemical devices used to monitor the presence or attainment of one or more of the parameters required for a satisfactory sterilization process, or is used in specific tests of sterilization equipment. The common principle is that the chemical indicator will change its color once the desired parameter is attained. They are of 6 classes of chemical indicators.

- **Class 1** Process Indicators
- **Class 2** Indicators for use in Specific Tests (equipment control indicator, BD test)
- **Class 3** Single Variable Indicators
- **Class 4** Multi-variable Indicators
- **Class 5** Integrating Indicators
- **Class 6** Emulating Indicators

Class 1 indicator :(Process indicator)

- Also called *External indicator* as- Used on external surface of each pack to indicate that the pack has been directly exposed to the sterilization process.
- Also called as *Exposure Control indicator* as they determine the pack has been exposed to the desired heat or not.
- E.g., autoclave tapes, indicator tapes etc.
- They distinguish between processed and unprocessed units
- Does not assure sterility

Class 2 indicator: (equipment control indicator)

- Testing sterilizer performance
- It used only for dynamic-air removal sterilizers (i.e., vacuum assisted sterilizers). It is not used for gravity type sterilizers.
- Bowie-Dick Test monitors efficacy of air removal and steam penetration
- It must be used daily before the first load i.e empty run.
- If unsatisfactory check for any corrections, Then subsequent 3 loads should be passed to confirm the efficacy of the device

Class 3 is a single parameter indicator so it's obsolete

Class 4 indicator (multi variable indicator)

- Also called as Internal indicator- as it is used inside each pack
- Designed to measure to two of the critical variables: Time, steam quality and temperature
- Indicates exposure to a sterilization cycle at stated values of the chosen variables
- Must to use in each pack/ tray *Class* 5 *indicator: (Integrating indicator)*
- Also called as Internal indicator- as it is used inside each pack
- Measures all three parameters- Time, steam quality and temperature
- Let you know if conditions for sterilization have been met in each pack
- It approximates the response of biological control
- Desirable to use in each pack/ tray
- Must to use during critical surgery
- The moving front format of this indicator helps the interpretation easier rather than the colour change used in other indicator
- The surgical team verifies the indicator just before the surgery. If it fails, then the tray is called back to CSSD.
- The class V indicator can be attached with patient case sheet as a proof of sterilization quality of the instruments used in surgery.

Biological indicator:

- Test system containing viable microorganisms providing a defined resistance to a specified sterilization process.
    - *Geobacillus stearothermophilus* for autoclave and plasma sterilizer
    - *Bacillus atrophaeus* for ETO
- Self-contained spore strip in ampoule
- Results directly applicable to bioburden of medical instrument
- Longer times needed for results (2-3 days). However newer devices are available which can detect results in 2-3 hours.
- Desirable to use with each load.
- Must to use once a day/week.
- Must to use along with implants.
- It acts as load control, if unsatisfactory recall has to be made and all the packs in that loads for which the B.I used as a control as all of these should be considered unsatisfactory for surgery.

Process challenge device: (PCD)

It's a 16 layer packing material where 8 folds above and 8 folds below are made in between which either a biological indicator or the chemical class 5 indicator is kept.

- A PCD containing a BI is referred to here as a BI challenge test pack
- A PCD containing only a Class 5 integrating indicator is referred to as a Cl challenge test pack.

Frequency of monitoring

- Yearly - Calibration & Maintenance - Physical
- Monthly - Routine maintenance - Physical
- Weekly - Leak test - Physical
- Every load - digital displays, gauge, record charts, printouts of the sterilizer equipment- Physical
- Daily once, before first run - BD test
- Every load - Class 5 chemical indicator with porous PCD - Steam
- Every load - BI test in case of implant load.
- Every pack – Class 1, Class-5 - for steam
- Every pack - Class 1 & class 4 -for EO.
- Daily once - BI test - Steam & EO

f.Recall Procedure*:

- Whenever a breakdown in the sterilization system is noted all packs sterilized by the faulty machine is immediately called back from the respective area where the sterile packs has been supplied.
- The packs called back are sent for re sterilization using a proper machine**.**

Maintenance and Repairs

- Machinery and equipment should be checked, cleaned and repaired routinely
- Urgent repairs should be carried out at the end of the days list
- Air conditioners and suction points should be checked, cleaned and repaired on a weekly basis.

Preventive maintenance on all theatre equipment to be carried out weekly and major work to be done at least once every year

Maintainance of Documents:

1. CSSD receipt register
2. CSSD issue Register
3. Equipment Maintenance Record
4. Equipment Calibration Record

1. Equipment Break down Record.

Policy on Biomedical waste management

Purpose:

- The purpose of this waste management policy is to outline safe and efficient practices for the segregation, store and disposal of biomedical and general waste generated by the hospital.

Scope:

- Biomedical waste is generated in all patient areas and needs to be managed as per the applicable statutory regulations.
- Training of health care workers on biomedical waste management
- To perform regular audit for quality improvement.

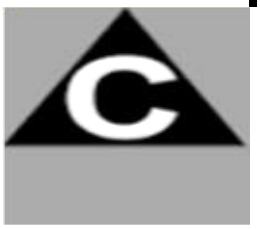
Biomedical waste management policy at SVIMS Hospital has been implemented in accordance with the rules of Biomedical Waste Management Act (BMW rules 2016). The hospital has got the consent to operate under pollution control board. The organization ensures Bio-Medical Waste is stored and transported to the site of treatment and disposal in properly covered vehicle within stipulated time limit in a secured manner.

SCHEDULE IV
(See rule 8(3) and (5)
LABEL FOR BIOMEDICAL WASTE COMNTAINERS OR BAGS

Part A

Figure – 1: A) Biohazard symbol and cytotoxic hazard symbols

HANDLE WITH CARE



HANDLE WITH CARE

Part B

LABEL FOR BIOMEDICAL WASTE COMNTAINERS OR BAGS

Waste category Number……
Day…….Month……
Waste quantity…….
Year ……

Sender's Name & Address
Receiver's Name & Address

Phone Number…
Phone Number…

Fax Number…….
Fax Number…….

Contact Number…….
Contact person…….

In case of emergency please contact:

Name & Address:

Phone No.

Note; Label shall be non –washable and prominently visible

B) Label for transporting biomedical waste

SVIMS HOSPITAL adopts color coded segregation of biomedical waste in all patient care areas.

All waste containers are emptied when they are 3/4ths full.

b. SEGREGATION OF BIO-MEDICAL WASTE*: Segregation is done at source. A color code is followed and appropriately coded waste bags are placed in bins in all patient care areas. **Bio-Medical wastage segregated in different color coded bags in the Institution example**

- ¬ All plastic goods: Red color bags.
- ¬ All infected material, cotton gauze etc., in yellow bag.
- ¬ All Kitchen and general waste in green/black bag.
- ¬ All sharp material in white container with 10% hyper solution.
- ¬ During segregation all staff followed hand hygiene, personal protective equipment.

SVIMS Hospital Bio-Medical Waste is handled by the authorized agency thorough M/s.AWM Consulting Limited., Tirupathi recognized by the A.P.Pollution Control Board.

- ¬ All Bio-Medical Waste is monitored by infection control team, and also monitored by Hospital Infection Control team daily monitored by Hospital infection control nurse.

c. Segregated bio medical waste is stored and transported* to the central waste collection area of the hospital in proper covered containers in secured manner.

- ϖ Waste from various patient care areas is removed twice a day or more if necessary. All bags that are being transported to the central waste collection area will have to be tied at the mouth to avoid spillage during transport.
- ϖ Smaller bags are collected into larger bags and carried by the on-duty housekeeping staff to designated storage areas on trolleys. Bags should be picked up and then transported before become completely fill.
- ϖ Avoid the transport of too many bags at one time and contact of the bag with the body of personnel.
- ϖ Avoid mixing of segregated wastes
- ϖ The staff is provided with personal protective equipment (PPE)

DISPOSAL OF CONTAMINATED NEEDLES AND SYRINGES

- ϖ Contaminated needles are destroyed using a needle destroyer. Contaminated syringes are put in puncture proof container (white)
- ϖ At segregation, syringes are put in blue color coded plastic cover
- ϖ Contaminated syringes are put in puncture proof container (white)

Category	ϖ Type of waste	ϖ Type of Bag/ container	ϖ Treatment/ Disposal options
ϖ Yellow	ϖ Human anatomical waste	ϖ Yellow coloured non chlorinated plastic bags	ϖ Incineration/ Plasma pyrolysis/ deep burial
	ϖ Animal anatomical waste		
	ϖ Soiled waste	ϖ	ϖ Incineration/ Plasma Pyrolysis/ deep burial/ autoclaving or hydroclaving + shredding/mutilation
	ϖ Expired/ discarded medicines-pharmaceutical waste, cytotoxic drugs	ϖ Yellow coloured containers/ non chlorinated plastic bags	ϖ Incineration (cytotoxic drugs at temperature > 1200□C)
	ϖ Chemical waste	ϖ Yellow coloured containers/ non chlorinated plastic bags	ϖ incineration or Plasma pyrolysis or Encapsulation
	ϖ Discarded linen contaminated with blood/ body fluids	ϖ Non-chlorinated yellow plastic bags/ suitable packing material	ϖ Non-chlorinated chemical disinfection followed by incineration/ plasma pyrolysis

	ϖ Microbiology, other clinical lab waste, blood bags, live/ attenuated vaccines	ϖ Autoclave safe plastic bag/ container	ϖ Pre-treat to sterilize with non-chlorinated chemicals on-site as per NACO/ WHO guidelines + ϖ Incineration.

Category	Type of waste	Type of Bag/ container	Treatment/ Disposal options
Red	Contaminated Waste (Recyclable)	Red coloured non-chlorinated plastic bags or containers	• Autoclaving/ micro-waving/ hydroclaving + shredding • Mutilation/ sterilization+ shredding. Treated waste sent to registered or authorized recyclers or for energy recovery or plastics to diesel or fuel oil or for road making,

White(Translucent)	Waste sharps including Metals	Puncture proof, Leak proof, tamper proof containers	• Autoclaving/ dry heat sterilization+ shredding/ mutilation • Encapsulation in metal container or cement concrete • Sanitary landfill/ designated concrete waste sharp pit

Blue	**Glassware,Metallicbody implants**	• Glass test tubes • Empty glass bottles • Contaminated glass bottles • Broken glass ampoules containing discarded/ Expired medicines except chemotherapeutic medicines • Metallic body	Disinfection (by soaking the washed glass waste after cleaning with detergent and Sodium Hypochlorite treatment)/ through autoclaving/ microwaving/ hydroclaving + recycling

	implants • Reusable glass slide

SOURCE OF WASTE: Sources are from various wards like Casualty, MICU, RICU, all O.T's, Recoveries, Laboratories, CathLab, Bio-Technology, Anatomy etc.

COLLECTION OF WASTE: A simple and clear notice describing which waste should go to which container, either poster or notice to be pasted on the nearer area. The entire container should have Bio-Hazard symbol. SVIMS has a notice in local language. Preferably, it should have drawing co relating the container, in appropriate colour with the kind of waste it should contain.

The BMW is collected in different categories in all areas twice by 06.00AM and 12.00 noon and they are transported to intermediate storage area. General waste stored in the dump yard. The bags are labeled with ward name signature with date. Stored red, blue and yellow bags handed over to Bio-Medical Staff

After collection of Bio-Medical Waste handed to M/s.AWM Consulting Limited, Tirupathi. In each shift collect the garbage and stored it in intermediate storage area from their sent for final treatment and disposal. In the same manner each shift we collect general garbage stored it in dumping yard and sent for Municipal dumping yard. Copies enclosed for kind perusal.

SAFE DISPOSAL OF WASTE:

- The bag or container should not fill more than ¾ th.
- It should be without any puncture/leakage.
- The container should have cover & cover can be removed without any difficulty.
- After collection from various wards, OTs and Recoveries, it is stored in covered intermediate storage area before they are finally taken / transported to the final treatment or disposal site.

- Untreated waste cannot be stored more than 48 hours.
- Adequate precautions were taken to avoid occupational hazards or environmental problem.

OTHER REUSABLE WASTE: There is no reusage of collected material as the segregated waste handed over to AWM Consulting Limited, the agency authorized by A.P.Pollution Control Board.

d.Bio Medical Waste treatment facility*.

The hospital has tie- up with We handed over the Bio-Medical Waste to authorized by the A.P.Pollution Control Board to M/s.AWM Consulting Limited, Tirupathi.

The waste is collected from the collection area of hospital by AWM workers and transported in a covered vehicle to the treatment facility.

The hospital conducting periodic visit to M/s.AWM Consulting Limited facility to ensure waste disposal according to BMW rules 2016.

Annual report of waste generated is maintained by administration and report submitted to Pollution Control Board.

e. All categories of staff handling bio medical waste are using appropriate personal protective measures*.

All the staff is using personal protective equipment during Bio-Medical waste management Eg: Mask, Gloves and also hand hygiene.

SVIMS Hospital maintains day to day records related to infection control/Bio-Medical Waste management. Apart from this we also maintain weekly and cleaning and fogging with eco shield.

All wards, ICU's, Special Rooms are cleaned with bleach water and disinfectant (2% Lysol) solution.

TOILET CLEANING RECORD IN SVIMS

- Working from Clean areas to dirty areas.
- Remove soiled linen from floor, Wipe up any spills, Remove waste.
- Clean door handle and frame, light switch.
- Clean chrome wall attachments.
- Clean inside and outside of sink, Sink faucets and mirror, wipe plumbing under the sink, apply disinfectant to interior of sink , ensure sufficient contact time with Disinfectant, rinse sinks and dries fixtures.
- Clean support railing, ledges/shelves.
- Clean bedpan support entire toilet including handle and underside of flesh rim Ensure sufficient contact and disinfectant.
- Report mould and cracked, leakage or damaged areas for repair.
- Change all color coded waste bags, clean color coded bin.
- Immerse mop in cleaning solution and clean the floor.
- Regularly we use soap solutions Lysol, detol, cleaning acid, bleach and lime powder depends on the condition.

PEST CONTROL SERVICES:

- Pest Control Services is an integral components of sanitation services for Hospitals

The following points should be taken in to consideration:

PEST EVALUATION:

- Rat, Cockroach, Mosquitoes, flies, bedbugs, termite

CHEMICALS DETAILS:

- Name of the chemical, name of the company, concentration, chemical composition, batch number, manufacturing date and expiry date.
  Vendor license – Plant protection officer, ministry of agriculture Govt of Delhi.
- Quality Control
- Records of application
- Emergency calls
- Monthly feed back

SVIMS SANITATION CHECK LIST / SANITATION AUDIT REPORT

Areas	Ist Shift Total No. of Workers Supplied	2nd Shift Total No of workers supplied	Night Shift Total No. of Workers supplied	Moping and washing	Cleaning Solutions (Soap oil,	Disinfectants (Bleach solution, Black phenol, Lysol)	Remarks/Repairs
OP Block							
IP Block							
IPW							
SPMC(W)							
All Hostels							
Faculty and Staff Quarters							
Outside and Public area							
Patient attendant Block							
CON							
COP							
Bio-Technology							
Bio-Medical Waste Management and							
Collection and Disposal of General Garbage							
Water analysis							
Hygiene and Health training Programme for workers.							

Fogging							
Fire safety							
Work place Safety							
Balamithra (Creche) Faculty and Regular, Contract Staff							

- **Based on check list audit report prepared**

BIOMEDICAL WASTE SEGREGATION AUDIT FORM AT WARD, SVIMS.

Date	Ward	SEGREGATION bags	Available	Contents Inappropriate to the bag	Total No.of Items
		Yellow			
		Red			
Poster – Yes/No Spillage kit – *Mercury- Yes/No *Blood- Yes/No		Sharp box			
		Blue card board box			
		Black			

Date	Ward	SEGREGATION bags	Available	Contents Inappropriate to the bag	Total No.of Items
		Yellow			
		Red			
Poster – Yes/No Spillage kit – *Mercury- Yes/No *Blood- Yes/No		Sharp box			
		Blue card board box			
		Black			

Figure – 3: Biomedical Waste Segregation Audit Form at ward, SVIMS, Tirupathi.

BIOMEDICAL WASTE SEGREGATION AUDIT FORM AT COLLECTION CENTRE, SVIMS.

Date	Ward	SEGREGATION bags	3/4th full	Contents Inappropriate to the bag	Total No.of Items	Label	Tied
		Yellow					
		Red					
		Sharp box					
		Blue card board box					
		Black					

Date	Ward	SEGREGATION bags	3/4th full	Contents Inappropriate to the bag	Total No.of Items	Label	Tied
		Yellow					
		Red					
		Sharp box					
		Blue card board box					
		Black					

Figure -4: Biomedical Waste Segregation Audit Form at Collection Centre, SVIMS, Tirupathi.

BIOMEDICAL WASTE AUDIT FORM FOR HCW, SVIMS.

WARD **DATE & TIME :**

Biomedical Waste Segregation Bags .

- Availability Yellow bag : Y/N
- Availability red bag : Y/N
- Availability black bag : Y/N
- Availability Sharp bag : Y/N
- Availability blue card bag : Y/N

HCW Undergoing auditing :

1. 6.
2. 7.
3. 8.
4. 9.
5. 10.

S.No.	HCW type	Item to be segregated	Bag Used	Adherence to color code
01				
02				
03				
04				
05				
06				
07				
08				
09				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				
21				
22				
23				

Figure – 5: Biomedical Waste Audit Form for HCW, SVIMS.

Reference: Bio – Medical waste (Management and Handling) Rules, 2016

PEST CONTROL:

SVIMS hospital has a pest control programme and can be contracted to an approved pest control contractor.

Integrated pest management (1PM) is a targeted approach to pest control that focuses on proactive, nonchemical pest management techniques before employing chemical treatments as a last resort.

IPM focuses on proactive strategies like exclusion, facility maintenance, stringent sanitation practices and ongoing inspections to keep pests away.

If chemical treatments are needed, non-volatile and the least-toxic formulations are used, and only in precision-targeted areas.

PEST CONTROL SERVICES IN SVIMS, SPMC (W),IPW , IP & OP BLOCK, FACULTY & STAFF QUARTERS,ALL HOSTELS AND ALL PUBLIC AREA

Sl. No.	Particulars	Day
01.	01.IP Block & Outside surrounding	Monday
02.	01.OP Block 02.OP Surrounding 03.All quarters	Tuesday
03.	01.Bio-technology 02.Nursing College 03.Physiotherapy College & outside surrounding	Wednesday
04.	IPW & Medical College Outside surrounding	Thursday
05.	01.All Hostels & Surroundings	Friday
06.	01.Canteen surroundings, Patients Attendant Block, 2nd Choultry	Saturday
07.	01.Open drain outside garden area & inside garden area & inside garden area, Rain water pits, man wholes	Sunday

Fogging with Malathion& Nuvacron (50 ml Malathion+ 50 ml Nuvacron in 5 litres of Diesel)**:**

01. Once in 15 days

Inside Campus dt: 14.01.2017

Outside Campus dt: 15.01.2017

02. Inside Campus dt: 29.01.2017

Out side Campus dt: 30.01.2017

E WASTE/RADIATION POLLUTION (Rules 2011):
SOURCES:

- **Nuclear Radiation**
- **Radio Activity**
- **Ionizing Radiations**
- **Mining**
- **Tailing Refining and Fuel Fabrication Waste**
- **Spent Fuel**
- **UV –Radiation**
- **Computers (Condemned)**

¬ In SVIMS generally we are maintaining E-Waste stored in Black color bag/Black color container with labeling.

¬ It includes name of the department, number of E-Waste, Expiry date.

Once it expires, the same container or bags handed over to Bio-Medical Personnel.

References:

l. Nizam Damani, Didier Pittet. Manual of Infection Control and Prevention. University Press, Oxford; 2012.

2. Manual of prevention and control of healthcare associated infections; 2016. Lok nayak hospital, New Delhi.

3. Manual of Infection Control and Prevention. JaiPrakash Narayana Apex Trauma Centre. All India Institute of Medical Sciences, New Delhi.

Training of staff in infection control

Purpose:

- To ensure the availability of resources required for the infection control program.
- To conduct training of all health care personnel.

Scope:

- Conduct training programs for staff in infection control
- Documentation of training conducted to staff.
- Surveillance and monitoring.
- Develop action plan and function accordingly.

The hospital management ensures the availability of resources required for the infection control program.

a. Recommendations on resources for training activities for the staff:

The hospital administrator/head of hospital should:

- ¬ Provide adequate resources for effective functioning of the infection control programme to conduct training of all health care personnel and special training to Infection control professionals.
- ¬ SVIMS hospital had already implemented a Infection control manual to educate the staff for understanding about hospital infections.
- ¬ Resources in the form of Infection control committee are also existing for training and educating all health care personnel , training of all new employees as to the importance of infection control and the relevant policies and procedures and special training to Infection control professionals

Training Resources and materials:

a. Qualified Personnel for Infection Prevention control training to medical staff
b. Qualified Personnel for Infection Prevention control training to nursing/paramedical staff
c. Qualified Personnel for Infection Prevention control training to other staff (House-keeping/Sanitation, CSSD and fesey workers)

- ¬ Inventory of Infection Prevention control courses
- ¬ Provision of materials as training tools during training programs for medical doctors and nurses
- ¬ Adequate space and facilities to conduct training programs
- ¬ Adequate audio visual aids to conduct training programs

- ¬ Sufficient on line facilities and trained computer personnel for regular updates to the staff about training programs and courses.

Induction and an ongoing training for health care staff and workers to Control Transmission*:

All health care staff and workers should receive mandatory infection control training as part of their induction and on an ongoing annual basis.

It is particularly important that knowledge and skills and attitudes for good infection control practices are continually updated.

The training covers all the general principles of infection prevention and control .

- ¬ Provide training needs to all the levels of the staff through Instititional training awareness programmes, in-service education and on-the-job training

- ¬ To organize regular training programmes for the staff for essential infection control practices that are appropriate to their job description

- ¬ To provide periodic re-training or orientation of staff; and review the impact of training.
- ¬ Wards or respective department in service training program

- ¬ infection control seminars, workshops and symposia

Institutional training awareness programmes should monitor:

1. Hand hygiene

2. Personal protective equipment

3. Safe handling and disposal of sharps

4. Safe handling and disposal of waste

5. Managing blood and body fluids

6. Decontaminating equipment

7. Maintaining a clean clinical environment

8. Appropriate use of indwelling devices

9. Managing accidents like needle stick injury, blood & body fluid spillage etc.

<u>d. In service training programme for all staff to manage Hospital Infection Control:</u>

- Infection control program is usually directed by the SVIMS infection control team & committee

¬ Already existing training Programmes:

⎪ Hand hygiene programme

⎪ Blood borne Pathogens Awareness Training

⎪ Conducting regular monthly Group discussions and presentations

⎪ Provide continuous education on infection control

¬ **CME's on Hospital Infection Control were conducted yearly.**

Annual training and orientation programme sessions for All the Faculty (Regular/Adhoc) and residents

Type of the training	**Teaching module**
Continuous Medical education on infection control	1. A basic training course in the principles of infection prevention and control 2. Managing accidents due to Blood borne Pathogens 3. Surveillance and outbreak workshop 4. Practical exercises tests
Continuous Medical education on infection control	1. Hand hygiene 2. Personal protective equipment 3. Safe handling and disposal of sharps 4. Safe handling and disposal of waste 5. Appropriate use of indwelling devices 6. Practical exercises tests
Continuous Medical education on infection control	1. Maintaining a clean clinical environment 2. Managing blood and body fluids 3. Decontaminating equipment 4. Practical exercises tests
Continuous Medical education on infection control	1. Annual one-day revision and update 2. Acknowledge of the staff with certificates and badges
Certification programmes for full time ICPs only	

Annual training and orientation programme sessions for Nursing staff

Type of the training	**Teaching module**
1 day workshop	1. A basic training course in the principles of infection prevention and control 2. Hand hygiene 3. Personal protective equipment 4. Safe handling and disposal of sharps 5. Safe handling and disposal of waste 6. Appropriate use of indwelling devices 7. Managing blood and body fluids 8. Decontaminating equipment 9. Managing accidents due to Blood borne Pathogens 10. Surveillance and outbreak workshop 11. Maintaining a clean clinical environment 12. Practical exercises tests
1 day workshop	1. Annual one-day revision and update 2. Acknowledge of the staff with certificates and badges

Annual training and orientation programme sessions for Technical staff

Type of the training	**Teaching module**
1 day workshop	1. A basic training course in the principles of infection prevention and control 2. Hand hygiene 3. Personal protective equipment 4. Safe handling and disposal of sharps 5. Safe handling and disposal of waste 6. Appropriate use of indwelling devices 7. Managing blood and body fluids 8. Decontaminating equipment 9. Managing accidents due to Blood borne

	Pathogens 10. Surveillance and outbreak workshop 11. Maintaining a clean clinical environment 12. Practical exercises tests

Annual training and orientation programme sessions for CSSD and House-keeping/Sanitation

Type of the training	**Teaching module**
1 day workshop	1. A basic training course in the principles of infection prevention and control 2. Hand hygiene 3. Personal protective equipment 4. Methods of cleaning, disinfection, and sterilization 5. Maintaining a clean clinical environment 6. Practical exercises tests

1. National infection control guidelines 2016 Draft for Consultation
2. Hospital infection control guidelines, ICMR, 2016
3. CLABSI. Available at http://www.cdc.gov/HAI/bsi/bsi.html
4. CAUTI. Available at http://www.cdc.gov/HAI/ca_uti/uti.html
5. VAP. Available at http://www.cdc.gov/HAI/vap/vap.html
6. SSI. Available at http://www.cdc.gov/HAI/ssi/ssi.html .
7. CSSD forum standard operating procedure sterile service department
8. Hospital infection control guidelines-ICMR-2016
9. National treatment guidelines for antimicrobial use in infectious diseases

Annexure

SRI VENKATESWARA INSTITUTE OF MEDICAL SCIENCES, TIRUPATI

HOSPITAL INFECTION CONTROL COMMITTEE
HOSPITAL ACQUIRED INFECTION SURVEILLANCE FORM(ADULT)

Patient Name	Hosp. No	Age	Sex M/F	ICU/Ward
Department	Admitting Unit	Date of Admission		Dt of Adm to ICU
Provisional Diagnosis		Final Diagnosis		
Outcome	Transfer out to ward/Unit name & date	LAMA on	Discharged on	Expired on

Risk factors / Comorbities: (Circle features present at admission)

DM	HTN	CLD	CKD	HIV	Transplantation	Immunosuppression	Any other

Type of Surgery : **Date of Surgery:**

Type of Device used and Device days

Intervention	**Date of Insertion**	**Date of Removal**	**Re insertion**	**Removal**
Urinary Catheter				
Mechanical Ventilation/ ET tube				
Tracheostomy				
CVC-Jugular/ Subclavian/Femoral/PICC				
Surgical Site Drainage Tube				
Dialysis Sheath				

		HD -1	**D-2**	**D-3**	**D-4**	**D-5**	**D-6**	**D-7**	**D -8**	**D-9**	**D-10**	**D-11**	**D-12**	**D-13**	**D-14**	**D-15**
HAI	**Date**															
All	Temperature															
CAUTI	Catheter present															
	Suprapubic tenderness															
	Loin pain															
	*1.Urgency,															

	2.Frenquency, 3. Dysuria															
CLABSI	CL(Central line) present															
	Chills															
	Hypotension(SBP ≤ 90)															
VAE	MV(mechanical ventilator) present															
	PEEP $_{dm}$															
	FiO2 $_{dm}$															
	WBC count															
	New antibiotics															
SSI	Purulent discharge at site															
	Clinician's diagnosis															
	Tenderness,swelling,erythema,heat															
	**Abscess at site															

Daily Monitoring

- *To be reported only when urinary catheter is not in place
- ** Detected by physical exam/ histopathological exam/imaging dm-daily minimum

Microbiology Culture Report (Site specific culture and blood culture : to be filled even culture is negative

Date of Sample Collection	Sample	Organism isolated	Colony count	AST report

(S- sensitive, R- resistant, Ak- Amikacin, G- Gentamycin, CFS- Cefoperazonesulbactum, Ci-Ceftriaxone, Ca- CeftazidineCx- Cefoxitin, Ox- Oxacillin, M- Meropenam PIT-Piperacillin-tazobactemCf- Ciprofloxacin, N- Nitrofurantoin, E- Erythromycin, P-Pencillin, T- tetracycline)

BUNDLE CARE AUDIT

		D1	D2	D 3	D 4	D 5	D 6	D7	D8	D 9	D1 0	D1 1	D1 2	D1 3	D1 4	D1 5
Urinary Catheter care Bundle																
Closed drainage system																
Urinary catheter secured																
Drainage bag above floor level & below bladder level																
Catheter care (aseptic)	Hand hygiene															
	Vaginal/meatal care															
	Perineal care															
Single use glove while handling/emptying (No contact b/t jug and bag)																
Separate jug for collecting																
Assessment of readiness to remove-documented?																
Central line Bundle																
Daily aseptic CL Care during handling	Hand Hygiene															
	Alcohol hub decontamination															
	CHG 2% for dressing changes															
Any local signs of infection?																
Dressing changed?																
Assessment of readiness to remove-documented?																
Ventilator bundle																
Head end elevation 30^{o}																
Adherence to hand hygiene																
Daily oral care (CHG2%)																
Need of PUD prophylaxis assessed?																
DVT prophylaxis																
Assessment of readiness to																

remove-documented?															

ICN Name and Signature with date

SRI VENKATESWARA INSTITUTE OF MEDICAL SCIENCES, TIRUPATI

HOSPITAL ACQUIRED INFECFTIONSURVEILLANCE FORM (ADULT) Page -2

CAUTI(CATHETER ASSOCIATED UTI) Date of Event (DOE)-

1. Urinary catheter criteria	Patient has indwelling urinary catheter in place for >2 calendar days						Yes / No
	Or if removed: Urinary catheter was in place on the day of sample collection or the day before						Yes / No
2.Symptom criteria	At least one of the following						
	Fever >100.4°F	Suprapubic tenderness	Loin pain	Urgency	Frequency	Dysuria	Yes / No
3.Urine culture criteria	Positive Urine Culture Not more than two organisms with atleast one organism having ≥10^5 CFU/ml						Yes / No
4.Blood culture criteria	No symptoms Positive blood culture (with one matching organism to urine culture						Yes / No
Final Diagnosis	Symptomatic CAUTI(criteria-1+3) ☐ ABUTI(Asymptomatic bacteremia UTI) ☐ (Criteria-1+4)						

CLABSI (CENTRAL LINE ASSOCIATED BLOODSTREAM INFECTION) Date of Event(DOE)-

1.Central line criteria	Patient has central line in place for 2 days or more					Yes / No
	Or if removed: Central line was in place on the day of sample collection or the day before					Yes / No
2.Pathogen	Pathogen identified from one blood culture(Not related to infection at any other site)					Yes / No
3.Commensal Culture +ve& symptoms	Commensal grown from two blood cultures(Not related to infection at other sites)					Yes / No
	3a. (Adult) Atleast one	Fever ☐ (>100.4°F)	Chills ☐	Hypotension (SBP≤ 90 ☐		Yes / No
	3b.(<1 year) Atleast one	Fever ☐ (>100.4°F)	Hypothermia ☐ (96.8°F)	Apnea ☐	Brady-Cardia ☐	Yes / No
Final Diagnosis		LCBI-1 ☐ (1+2)	LCBI-2 ☐ (1+3a)	LCBI-3 ☐ (1+3b)	Date of Onset	

VAE (VENTILATOR ASSOCIATED EVENT):

MV criteria	Patient has mechanical ventilator(MV)in place for 2 days or more	Yes / No
	Or if removed:MV was in place on the day of sample collection or the	Yes /

	day before	No
Baseline	Patient has a baseline period of stability or improvement on the ventilator, defined by ≥2 days of stable or decreasing daily minimum PEEP(5or less)or FiO_2 (40% or less)	Yes / No
VAC	Increase in FiO_2dm by ≥20% for ≥2 days	Yes / No
	Or increase in PEEPdm by ≥ 3cm byH2O for ≥ days	
i-VAC	Temperature > 100°F or < 96.8°F, OR WBC ≥ 12,000 cells/mm or ≤ 4000 cells/mm	Yes / No
	And a new antimicrobial agent is started within 5 days of DOE, and is continued for ≥ 4 days	
P-VAP	Culture positive with significant growth (ET aspirate- $\geq 10^5$ CFU/M) (BAL, lung tissue or brush- 10^4) (brush - $\geq 10^3$)	Yes / No
	Direct smear- Purulent resp.secretions(PC>25/PF, EC≤10/LFP) AND Culture positive(any growth)(from sputum, ET aspirate, BAL, lung tissue or brush)	

Final Diagnosis	VAC (Ventilat associate condition)	i-VAC (Infection related ventilator associated complication)	P-VAP(Possible ventilat associated pneumonia)

SSI (SURGICAL SITE INFECTION) : **Date Of Event (DOE):**

1.	Patient had surgery within past 30 days or Surgery within 90 days if implant in place or breast, cardiac surgery or herniorraphy					Yes / No
2.	Wound class (Tick appropriate)	Clean	Clean contaminated	Contaminated	Dirty	
3.	PATOS (Present at the time of Surgery- Visible pus/ abscess at operation site: documented in OT note					Yes / No
4.	Any one of the following					
5.	SI-SSI (Superficial Incisional)	Any one of the following 1. Purulent drainage from superficial incision 2. Positive culture (pus/tissue) 3. Incision opened, culture not sent but patient has atleast one symptoms: pain or tenderness; localized swelling; eryth; or heat 4. Clinician diagnosis as S-SSI				Yes / No
	DI-SSI(Deep incisional)	Any one of the following 1. Purulent drainage from deep incisio 2. Positive culture (pus/tissue) 3. Incision dehiscence spontaneously or opened deliberately, culture not sent but patient has atleast one symptoms : fever (>100.4°F),pain tenderness 4. Abscess involving the deeper incision found at physical exam/histopath/imaging				Yes / No
	Organ/space SSI	Any of the following: 1. Purulent drainage from drain through organ or space 2. Positive culture(pus/tissue) from the discharge from drain/organ or space 3. Abscess involving the organ or space found at physical exam/ histopath/imaging				Yes / No

SRI VENKATESWARA INSTITUTE OF MEDICAL SCIENCES, TIRUPATI
HOSPITAL INFECTION CONTROL COMMITTEE

OPERATING ROOM SURVEILLANCE

Date _____ Time _____

Place _____

S.NO	CULTURE SITES	GROWTH	ORGANISM
1.	BOYLE'S MACHINE		
2.	OT TABLE		
3.	CIRCUIT		
4.	CEILING LIGHT		
5.	INSTRUMENT TROLLEY		
6.	DRUG TROLLEY		
7.	DIATHERMY TROLLEY		
8.	SLAB		
9.	HUMIDIFIER		
10.	SUCTION		
11.	A/C VENT		
12.	WALL		
13.	FLOOR		
14.	DOOR HANDLE		
15.	SPL.EQUIPMENT		
16.	SPL.EQUIPMENT		

HICC (HOSPITAL INFECTION CONTROL COMMITTEE),SVIMS
HAND HYGIENE AUDIT

Ward/ICU:

Availability of hand rubs at
ICU entrance- Yes/No
Bed side-_____no. of hand rubs available out of _____beds
Dressing and injection trolley _____ no. of hand rubs available out of_____ opportunities
Near the wash basin
Availability of hand wash: Y/N
Availability of paper towel: Y/N, Cloth towel- Y/N
If YES, then quantity for1 week: Enough /not enough

HCW type undergoing auditing-

1.	FM	Faculty Male	11.	TC-M	Technician Male
2.	FF	Faculty Female	12.	TC-F	Technician Female
3.	SR-M	Senior Resident Male	13.	TC Stu-M	Technician Student Male
4.	SR-F	Senior Resident Female	14.	TC Stu-F	Technician Student Female
5.	JR-M	Junior Resident Male	15.	DL-M	Daily Laborer - Male
6.	JR-F	Junior Resident Female	16.	DL-F	Daily Laborer - Female
7.	HN-F	Head Nurse - Female	17.	N.Stu-M	Nursing Student Male
8.	SN-M	Staff Nurse Male	18.	N.Stu-F	Nursing Student Female
9.	SN-F	Staff Nurse Female	19.		
10.	ANM	Auxiliary Nurse Midwife	20.		

WHO five moments of Hand rub/wash
1. Before touching patient
2. Before a procedure
3. After a procedure
4. After touching patient
5. After touching patient's surrounding

Indication of hand wash
6. Hands are visibly soiled
7. Before & after feeding
8. Before & after toilet
9. Before & after shift
10. Diarrhea patient

Steps of HR/HW: *0. Apply,1.Palm to palm 2.Back to palm3.Interlaces 4.Back of fingers 5. Thumb 6.Nails on palm7. Wrist8. Dry by paper towel 9. Close tap by non touch method (HR: 20-30 sec, HW:40-60 sec*

Date and time	**S. No**	**HCW type**	**HH MOMENT**		**Hand hygiene steps followed**			**Gloves**	
			HR	**HW**	**Not followed**	**Partially followed** (duration and steps not followed)	**Followed all Steps** (duration)	1.Used when indicated 2.Not used when indicated 3.Used when not indicated	Removed after single use
	e.g	FM						1	No

Date and time	S. No	HCW type	HH MOMENT		Hand hygiene steps followed			Gloves	
			HR	HW	Not followed	Partially followed (duration and steps not followed)	Followed all Steps (duration)	1.Used when indicated 2.Not used when indicated 3.Used when not indicated	Removed after single use
	e.g	FM						1	No

SRI VENKATESWARA INSTITUTE OF MEDICAL SCIENCES, TIRUPATI
HOSPITAL INFECTION CONTROL COMMITTEE

CARE BUNDLE FOR URINARY CATHETER

Patient Name: _____

Hospital No. _____

Insertion Bundle for Urinary Catheter Care

Date of Insertion _____

Sterile items/ equipment used: ☐ Yes No ☐

Catheter inserted using strict aseptic Non – touch technique: ☐ Yes No ☐

Closed drainage system: ☐ Yes No ☐

Catheter of appropriate size: ☐ es No ☐

Signature of the observer

Maintenance Bundle for Urinary Catheter Care

Day	Date	Daily catheter care by Aseptic technique (Vaginal care/Meatal care) + Perineal care			Closed Drainage system (Yes/No)	Drainage bag above floor & below bladder level	Catheter needed (Yes/No)	Signature
		6 am	12 noon	6 pm				
1.								
2.								
3.								
4.								
5.								
6.								
7.								
8.								
9.								
10.								

- Sterile guaze/cotton to be used for each care
- Wash with soap solution/Betadine and dry with wet guaze
- Single use gloves should be discarded after emptying drainage bag
- Hand hygiene before and after handling.

SRI VENKATESWARA INSTITUTE OF MEDICAL SCIENCES, TIRUPATI
HOSPITAL INFECTION CONTROL COMMITTEE

CARE BUNDLE FOR CENTRAL LINE

Patient Name: _____

Hospital No. _____ICU/Ward_____

Insertion Bundle for Central line care

Date of Insertion:_____ Elective / Emergency_____

1. Number of lumens in catheter:
2. Hand Hygiene performed: ☐ Yes ☐ No
3. Inserted using maximal sterile barrier precautions: Caps Yes ☐ / No ☐
   Mask Yes ☐ No ☐
   Sterile gown Yes ☐ / No ☐
   Sterile Glove Yes ☐ No ☐
4. Skin disinfected before insertion (2% Chlorhexidinegluconateand allow it to air dry completely) ☐ Yes / No ☐
5. Site of insertion: _____
6. Sterile drape used: Yes ☐ / No ☐
7. Blood aspirated freely: Yes ☐ No ☐
8. Whether insertion date is recorded at site of insertion? Yes ☐ No ☐
9. Semi permeable dressing used: Yes ☐ No ☐
10. Whether hands washed and dried after procedure? Yes ☐ / No ☐

Signature of Observer

SRI VENKATESWARA INSTITUTE OF MEDICAL SCIENCES, TIRUPATI
HOSPITAL INFECTION CONTROL COMMITTEE

MAINTENANCE BUNDLE FOR CENTRAL LINE

Day	Date	Daily Catheter Care by Aseptic Technique			Any local signs of infection	Whether dressing changed or not	CVC still required or not	Signature	
		Alcohol hub decontamination during handling	Hand hygiene before handling	Chlorhexidine gluconate 2% for insertion site dressing changes				Doctor	Nurse
1.									
2.									
3.									
4.									
5.									
6.									
7.									
8.									
9.									
10.									
11.									
12.									
13.									
14.									
15.									
16.									
17.									
18.									
19.									
20.									

- Hand hygiene before accessing devices
- Use sterile single use antiseptic devices

SRI VENKATESWARA INSTITUTE OF MEDICAL SCIENCES, TIRUPATI
HOSPITAL INFECTION CONTROL COMMITTEE

CARE BUNDLE FOR VENTILATOR

Patient Name: _____

Hospital No. _____ICU/Ward_____

Date of Insertion:_____

Maintenance Bundle for Ventilator Care

Day	Date	30° Head end elevation	Adherence to Hand Hygiene	Assessment of readiness to Extubate (Done or not)	PUD prophylaxis needed or not	DVT prophylaxis given or not	Daily oral care with Chlorhexidine			Suspec-ted VAP	Signature	
							6 am	12 Noon	6 pm		Doctor	Nurse
1.												
2.												
3.												
4.												
5.												
6.												
7.												
8.												
9.												
10.												
11.												
12.												
13.												
14.												
15.												
16.												
17.												
18.												
19.												

- Hand Hygiene before accessing devices
- PUD-Peptic Ulcer Disease

SVIMS SANITATION CHECK LIST / SANITATION AUDIT REPORT

¬ **Based on check list audit report prepared**

Areas	I[st] Shift Total No. of Workers Supplied	2[nd] Shift Total No of workers supplied	Night Shift Total No. of Workers supplied	Moping and washing	Cleaning Solutions (Soap oil,	Disinfectants (Bleach solution, Black phenol, Lysol)	Remarks/Repairs
OP Block							
IP Block							
IPW							
SPMC(W)							
All Hostels							
Faculty and Staff Quarters							
Outside and Public area							
Patient attendant Block							
CON							
COP							
Bio-Technology							
Bio-Medical Waste Management and							
Collection and Disposal of General Garbage							
Water analysis							
Hygiene and Health training Program me for workers.							
Fogging							
Fire safety							
Work place Safety							
Balamithra (Creche) Faculty and Regular, Contract Staff							

BIOMEDICAL WASTE SEGREGATION AUDIT FORM AT WARD, SVIMS.

Date	Ward	SEGREGATION bags	Available	Contents Inappropriate to the bag	Total No.of Items
		Yellow			
		Red			
Poster – Yes/No Spillage kit – *Mercury- Yes/No *Blood- Yes/No		Sharp box			
		Blue card board box			
		Black			

Date	Ward	SEGREGATION bags	Available	Contents Inappropriate to the bag	Total No.of Items
		Yellow			
		Red			
Poster – Yes/No Spillage kit – *Mercury- Yes/No *Blood- Yes/No		Sharp box			
		Blue card board box			
		Black			

BIOMEDICAL WASTE SEGREGATION AUDIT FORM AT COLLECTION CENTRE, SVIMS.

Date	Ward	SEGREGATION bags	3/4th full	Contents Inappropriate to the bag	Total No.of Items	Label	Tied
		Yellow					
		Red					
		Sharp box					
		Blue card board box					
		Black					

Date	Ward	SEGREGATION bags	3/4th full	Contents Inappropriate to the bag	Total No.of Items	Label	Tied
		Yellow					
		Red					
		Sharp box					
		Blue card board box					
		Black					

BIOMEDICAL WASTE AUDIT FORM FOR HCW, SVIMS.

WARD **DATE & TIME :**

Biomedical Waste Segregation Bags .

- Availability Yellow bag : Y/N
- Availability red bag : Y/N
- Availability black bag : Y/N
- Availability Sharp bag : Y/N
- Availability blue card bag : Y/N

HCW Undergoing auditing :

1. 6.
2. 7.
3. 8.
4. 9.
5. 10.

S.No.	HCW type	Item to be segregated	Bag Used	Adherence to color code
01				
02				
03				
04				
05				
06				
07				
08				
09				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				
21				
22				
23				

Surgical prophylaxis Audit

Patient details			
Name:	Age:	Gender:	I.D No:
Date of Admission:	Admission ward and bed number:		
Patient coming from : Home/ Institution/unknown			
Medical information			
Procedure carried out:		Date of Operation:	
Wound class(clean, 1 ; clean-contaminated, 2; contaminated, 3; dirty,4) :			
Co morbidities : (diabetes, COPD, CHF, corticosteroid use, blood transfusion, drains)			
Smoker :	Any surgical complications:		
Procedure specific prophylaxis:			
Generic name:	Administered dose:	Route of administration:	
Time of administration:	Duration of antibiotic prophylaxis :		
Time the agent was discontinued:	Appropriateness of prophylaxis :		

High-end antibiotic monitoring sheet

Name of the patient: Location:

Age/sex:

Diagnosis:

Meropenem, doripenem,
Imipenem, ertapenem,
Colistin, tigecycline

Linezolid,
Daptomycin
Teicoplanin
Vancomycin

Antibiotic presribed:

Definitive/empiric therapy:

Indication: Date started:

Suspected/ confirmed site of infection:

Blood culture report if available : yes / no

Site specific culture report if available : yes/ no

Community acquired/health care associated infection: (put tick)

Severity of illness, presence of shock :

REVIEW

- Second day
- Fifth day
- Tenth day

Comments by infection control team:

Feed back given to the doctor (if necessary):

USE OF PERSONAL PROTECTIVE EQUIPMENT (PPE) FOR CONTACT PRECAUTIONS
Audit

Facility: _____ Date: DD_____MM_____YYYY_____

Patient Unit:_____ Day of Week: S M T W Th F S

Auditor (print):_____ Start Time: ____:____ End Time: ____:____

Healthcare Worker Category (Circle #):

1 = Physician
2 = Nurse
3 = Healthcare Aide
4 = Social Worker
5 = Spiritual Care
6 = IV Team/DSM
7 = Physiotherapy
8 = Occupational Therapy
9 = Housekeeping
10 = Patient Transport
11 = Radiology/DI Technician
12 = Respiratory Therapy
13 = Dietary
14 = Speech Language / Audiology
15 = Rec. Therapy
16 = Pharmacy
17 = Other

Instructions: Select ''Y'' if activity was observed and completed appropriately; select "N" if activity was observed and not completed appropriately. Select "Not observed" if you were not able to observe the activity.

Bed/Bed Space Location or Number _____

ITEM	COMPLIANCE		
Setup			
1. Precaution signage visible before entering the room or bedspace	Y	N	Not observed
2. PPE supplies available immediately outside room or bedspace	Y	N	Not observed
Putting On PPE			
3. Hand hygiene is performed immediately prior to putting on PPE	Y	N	Not observed
4. New single use PPE applied prior to entering room/space	Y	N	Not observed
5. PPE applied in appropriate sequence: A. Gown B. Gloves	Y	N	Not observed
6. Gown worn as indicated by Contact Precautions			
7. Appropriate type of gown is worn (i.e., yellow isolation gown)	Y	N	Not observed
8. Gown securely tied at the neck and then waist	Y	N	Not observed
9. Gloves worn as indicated by Contact Precautions	Y	N	Not observed
Use of PPE			
10. PPE is only worn inside the isolation room/space	Y	N	Not observed

Taking Off PPE			
11. PPE is removed within the isolation room	Y	N	Not observed
12. PPE is removed in a manner to prevent contamination	Y	N	Not observed
13. PPE is removed in appropriate sequence: A. Gloves and gown removed B. Hand hygiene performed immediately after removal of PPE	Y	N	Not observed

ACCIDENTAL EXPOSURE RECORD

When completed, please return the form to the Staff Health Department

This form should be completed for every case of needle or **sharp injury, or when there has been mucocutaneous contamination of blood and body fluids**, by the Staff Health Department or the doctor in Accident and Emergency outside normal working hours.

Name _____ DOB _____

Occupation _____ Hospital _____ Ward/Dept _____

Date _____ Time _____

Site of injury _____

Immediate management, eg.wound washed and bled? Yes / No

1. Accidental injection ☐

2. Sharp instrument/needle stick

- Splash to eye/mouth ☐
- Suture needle ☐
- Splash to broken skin ☐
- Hollow needle ☐
- Bite/Scratch ☐
- Other (specify) ☐

Material

1.Blood/Plasma ☐ 2.Serum rich fluid/CSF ☐

3.Urine ☐ 4.Saliva ☐

5.Bite/Scratch ☐ 6.Other (Specify) ☐

How it occurred

1.Giving medication ☐ 2.Surgery /Delivery ☐

3.Bite/ Scratch ☐ 4.Venepuncture ☐

5. Re-capping ☐

Comments:

Section B: Details of the Recipient

Hepatitis B vaccination status

Full Course ☐ Incomplete course ☐ No vaccination ☐

Date of last dose _____

Response to vaccine: Good(>100 IU) ☐ Partial (10-100 IU) ☐

No response (<10 IU) ☐ Not known ☐

Section C : Donor/ Source

Source Unknown ☐ Source known ☐

Patient's name_____ DOB _____

Hospital No._____

Infective status already known

Hepatitis B positive ☐ Yes ☐ No

Hepatitis C positive ☐ Yes ☐ No

HIV positive ☐ Yes ☐ No

Or if infective status not known

Risk Category of Donor: Hepatitis B ☐ **Low** ☐ **High**

(To be assessed by medical practitioner) Hepatitis C ☐ **Low** ☐ **High**

HIV ☐ **Low** ☐ **High**

Section D : Course of Action

1. Blood sample taken from donor (consent obtained for testing) ☐ Yes ☐ No
2. Initial counseling given: in person ☐ Yes ☐ No
   via telephone ☐ Yes ☐ No
3. Hepatitis B vaccination given: 1st dose Booster
4. Blood taken from recipient for HBs Ag titres + serum saved ☐ Yes ☐ No
5. Anti-HB immunoglobulin ordered/given ☐ Yes ☐ No
6. HIV post exposure prophylaxis commensed ☐ Yes ☐ No
7. Referral made to Staff Health Dept ☐ Yes ☐ No

Signature of Nurse / Doctor _____ Date _____ Time _____

Test Results _____ Recipient _____ Source _____

Please return the form to Staff Health Department

List of Abbreviations

% - Percentage

°C - Degree centigrade

ABC/3TC - Abacavir/lamivudine

Ag - Antigen

AIIR - Airborne Infection Isolation Room

ATV/r – Atazanavir/ ritonavir

CA-MRSA - Community associated-methicillin-resistant *Staphylococcus aureus*

CDC - Centre for Disease Control and Prevention

cm - Centimetres

EFV - Efavirenz

ESBL - Extended-spectrum β lactamase

GNB - Gram negative bacilli

HAI - Hospital acquired infections

HCV - Hepatitis C virus

HCW - Health care workers

HEPA - High efficiency particulate air

HICC - Hospital Infection Control Committee

HIV - Human immunodeficiency virus

HME - Heat and moisture exchanger

ICU - Intensive care unit

IM - Intramuscular

IU - International unit

IV - Intravenous

kg - Kilograms

LPV/r – Lopinavir /ritonavir

MDRO - Multidrug-resistant organisms

MDRSP - Multidrug-resistant *Streptococcus pneumoniae*

MDR-TB - Multidrug-resistant tuberculosis

ml - Millilitres

MRSA - Methicillin resistant *Staphylococcus aureus*

pH - Negative logarithm of hydrogen ion

PPE - Personal Protective Equipment

RAL - Raltegravir

TDF/FTC - Tenofovir/emtricitabine

TB - Tuberculosis

VAP - Ventilator associated pneumonia

VISA - Vancomycin intermediate *Staphylococcus aureus*

VRE - Vancomycin resistant Enterococci

VRSA - Vancomycin resistant *Staphylococcus aureus*

WHO - World Health Organization