

**EUNETIPS Survey on guidelines or recommendations or official rules about the air quality in operating theatres in Europe**

# EUNETIPS

European network to promote infection prevention for patient safety

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	PT		Associação Portuguesa de Infecção Hospitalar (APIH) <i>João Barranca</i>
	RO		Romanian Society of Microbiology (RSM) <i>Licker Monica</i>
	RS		Serbian Association of Prevention and Infection Control (SAPIC) <i>Markovic Ljiliana</i>
	ES		Spanish Society for Prevention Medicine, Public Health and Hospital Hygiene (SEMPSPH) <i>Asensio Vegas Angel</i>
	SE		Swedish Association for Infection Control (SAIC) <i>Maria Tholander- Hasselrot</i>
	UK		British Infection Association (BIA)
	UK		Healthcare Infection Society (HIS) <i>Martin Kiernan</i>
	UK		Infection Prevention Society (IPS) <i>Helen O'Connor</i>
	UK		Royal College of Nursing (RCN) <i>Rose Gallagher</i>

## EUNETIPS Survey on Guidelines or Recommendations or Official rules about the air quality in operating theatres in Europe

Air is a potential source of contamination in the operating theatre. Following the Medical Research Council Study showing a correlation between microbial air contamination and the incidence of surgical site infections in prosthetic joint surgery, the British National Health Service published guidelines for the design and ventilation of operating theatres and for threshold values for both ultraclean (with unidirectional airflow system) and conventional (with turbulent airflow) operating theatres. However, there is no international consensus on tolerable limits of microbial air contamination, and there are no generally accepted methods and frequencies for air sampling.

On the occasion of the International Congress on Aerobiology ([www.ica2018.eu](http://www.ica2018.eu)), which will be held in Parma on September 3-7, 2018, it is proposed to present the results of this EUNETIPS survey, aimed at knowing whether in the European countries guidelines/recommendations/official rules on air quality in operating theatres, regarding in particular threshold values and microbial and/or particle air monitoring, are available.

We will be grateful if you could send back the filled form by June 25.

If further details and/or clarifications are needed, please contact:

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Country:

Your answer

Are guidelines/recommendations/official rules on air quality in operating theatres available in your Country?

Yes

No

## Respondent Countries (12/20, 60%)

AUSTRIA



DENMARK



ESTONIA



FRANCE



GERMANY



UNITED KINGDOM



ITALY



NEDERLAND



POLAND



ROMANIA



SPAIN



SWEDEN



**Are guidelines / recommendations / official rules on air quality in operating theatres available in your Country?**

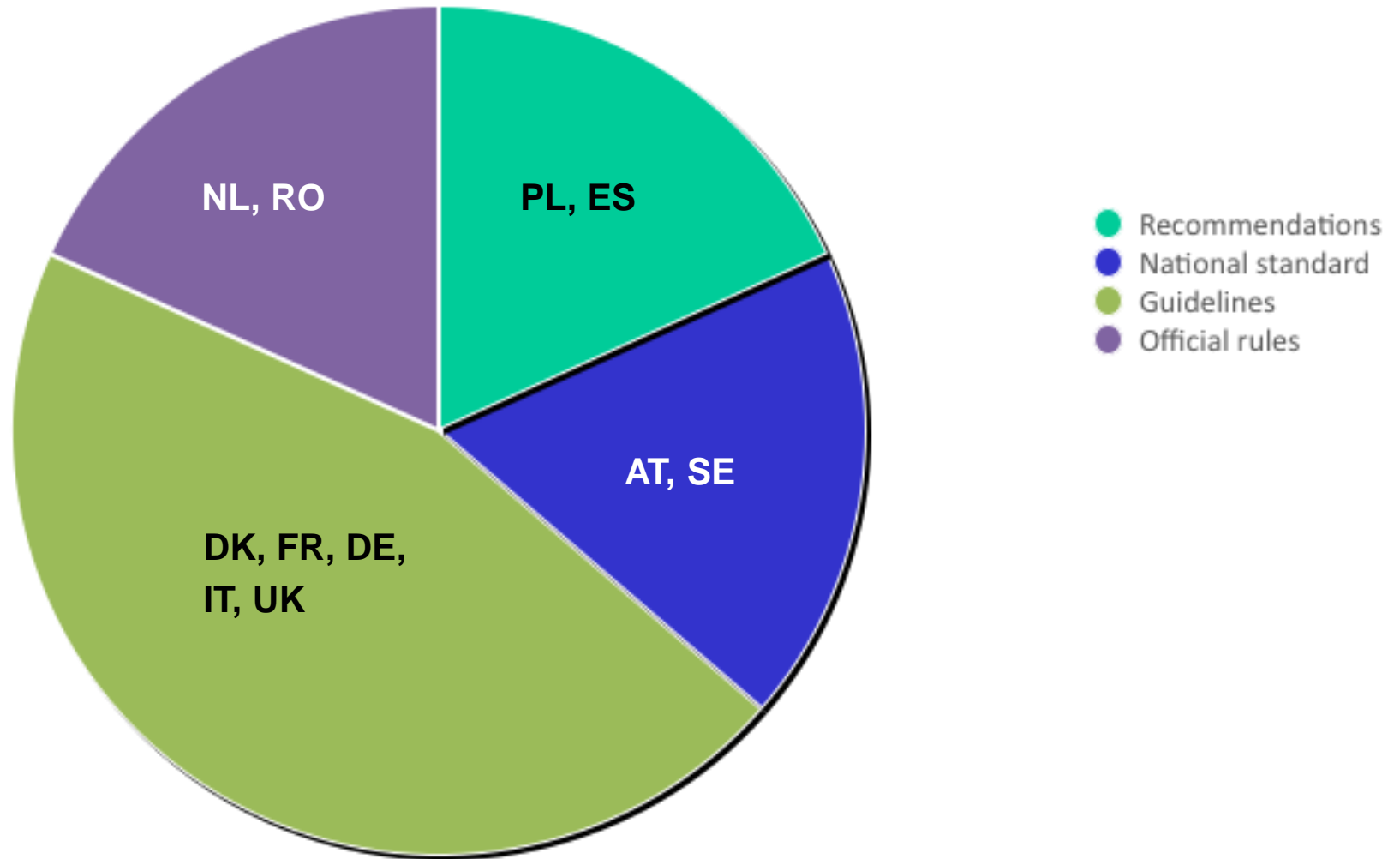
**YES: 11**

(Austria, Denmark, France, Germany, Italy, Netherlands, Poland, Romania, Spain, Sweden, United Kingdom)

**NO: 1**

Estonia

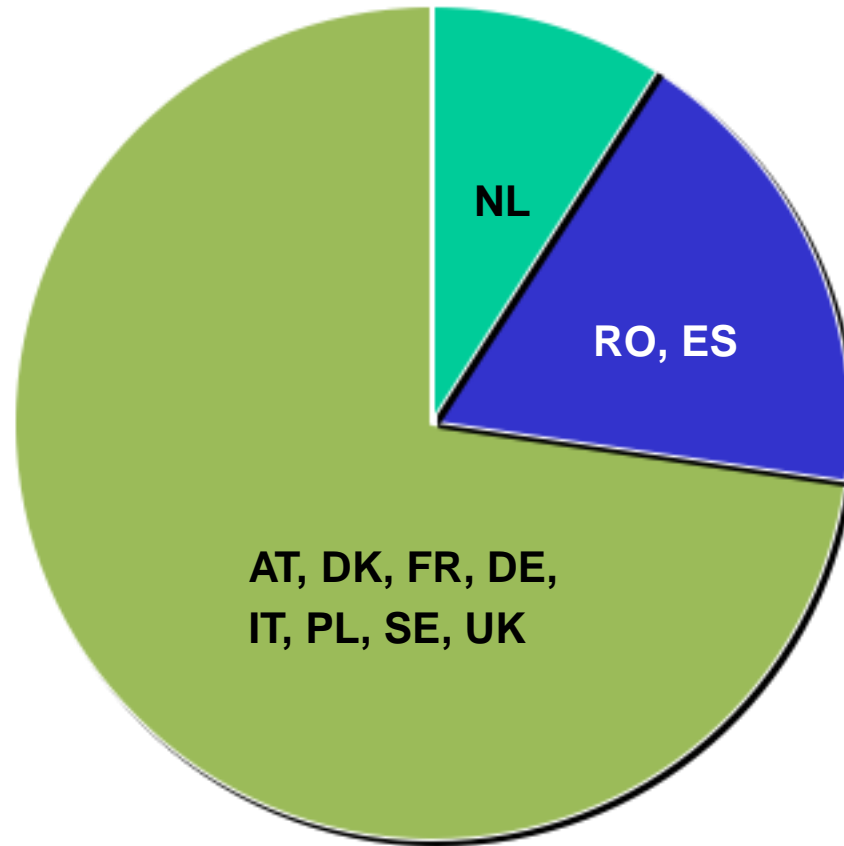
# What is available?



**Which institution published these guidelines / recommendations / official rules?  
 In which year were they published? If they have been reviewed, in which year?  
 Are they available online? If yes, please submit the internet link to the document**

	<b>Institution</b>	<b>Publication</b>	<b>Review</b>	<b>Link submitted?</b>	<b>Open access?</b>
AT	<b>Austrian Standard Institute</b>	2014	2015	✓	✗
DE	<b>DGHM</b> (German Society of Hygiene and Microbiology)	1989		✗	✗
	<b>DIN</b> (German Institute for Standardization)	2008	2018	✗	✗
	<b>KRINKO</b> (Commission for Hospital Hygiene and Infection Prevention) ( <b>RKI</b> )	2018		✓	✓
DK	<b>SSI</b> (Statens Seruminstitut under auspices of the Danish Ministry of Health) and <b>FSTA</b> (Forum for hospital technique and architecture)	2014		✓	✓
ES	<b>Ministry of Health</b>	1999	2010	✓	✓
FR	<b>French Society for Hospital Hygiene (SF2H)</b>	2015	2018	✗	✓
IT	<b>ISPESL</b> (Istituto Superiore per la Previdenza e la Sicurezza sul Lavoro, National Institute for Occupational Safety and Prevention)	1999	2009	✓	✓
NL	<b>RIVM</b> (National Institute for Public Health and the Environment)	2014		✓	✓
PL	Expert group	2017		✓	✓
RO	<b>Ministry of Health</b>	2006	2016	✓	✓
SE	<b>SIS</b> (Swedish Standard Institute)	2012	2015	✗	✗
UK	<b>Government</b>	2007		✓	✓

**Do these guidelines / recommendations / official rules deal with:**

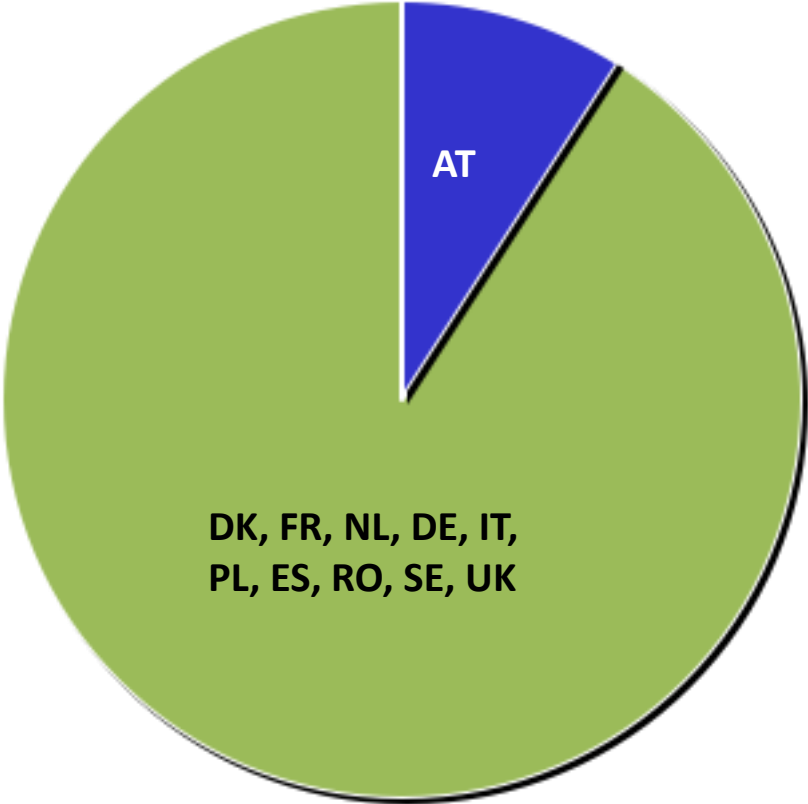


● Unidirectional airflow OT

● Conventional OT

● Both

**Do these guidelines/ recommendations / official rules refer to:**



● Microbial contamination

● Particles contamination

● Both



## **If the guidelines deal with particles air contamination, do they refer to ISO 14644-1?**

**YES: 7**

(AT, FR, IT, NL, PL, ES, UK)

**NO: 4**

(DK, DE, RO, SE)

## **If they don't refer to ISO 14644-1, which references are considered?**

**Denmark:** ISO 14644-3, EU GMP

**Germany:** German guidelines

**Romania:** no answer

**Sweden:** "Method for Limitation of Risks", published in 1993, 1995 and 2002 by Ljunqvist and Reinmüller

When is particle sampling (**P**) recommended?

When is microbial air sampling (**M**) recommended?

	At commissioning	At rest	During activity	Epidemics	Renovations	Other
AT	P	P			P	P
DE	P	PM	M		P	
DK	P	P	M	PM	PM	
ES		PM		PM	PM	
FR		PM	P	M	PM	PM
IT		PM	PM	PM	PM	PM
NL		P	M		P	PM
PL	P	M	M	M	PM	
RO		M	M	M	PM	
SE	PM		M	M	M	
UK	PM				PM	

## «OTHER»

### **France**

*Particles:* See comment of Recommendation 11.

*Microbes:* Routine microbial air sampling are not recommended (recommendation 12, 33)

### **Italy**

*Particles:* Evaluate the correct functioning of HVAC system, Assessment in case of epidemics.

*Microbes:* In case of quality assessment programmes, When evaluating compliance to behavioural procedures, After HVAC system maintenance (e.g. filter change)

### **Netherlands**

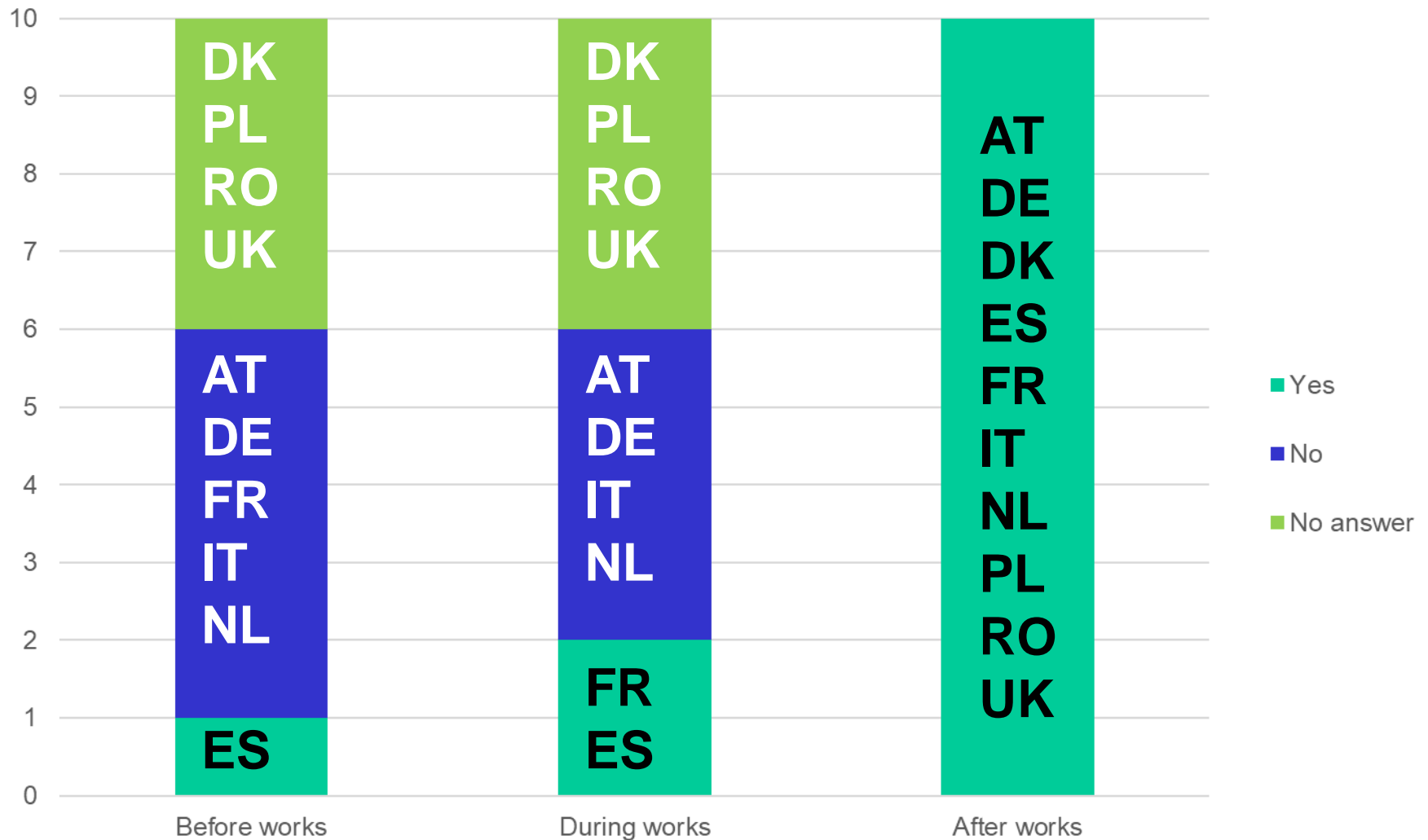
*Particles:* Particle sampling is done to define a clean area in the OR, to be done in a new OR and when renovated.

*Microbes:* There is a new recommendation about microbial sampling in preparation. This is a sample during surgical activity, you are not obliged to do this.

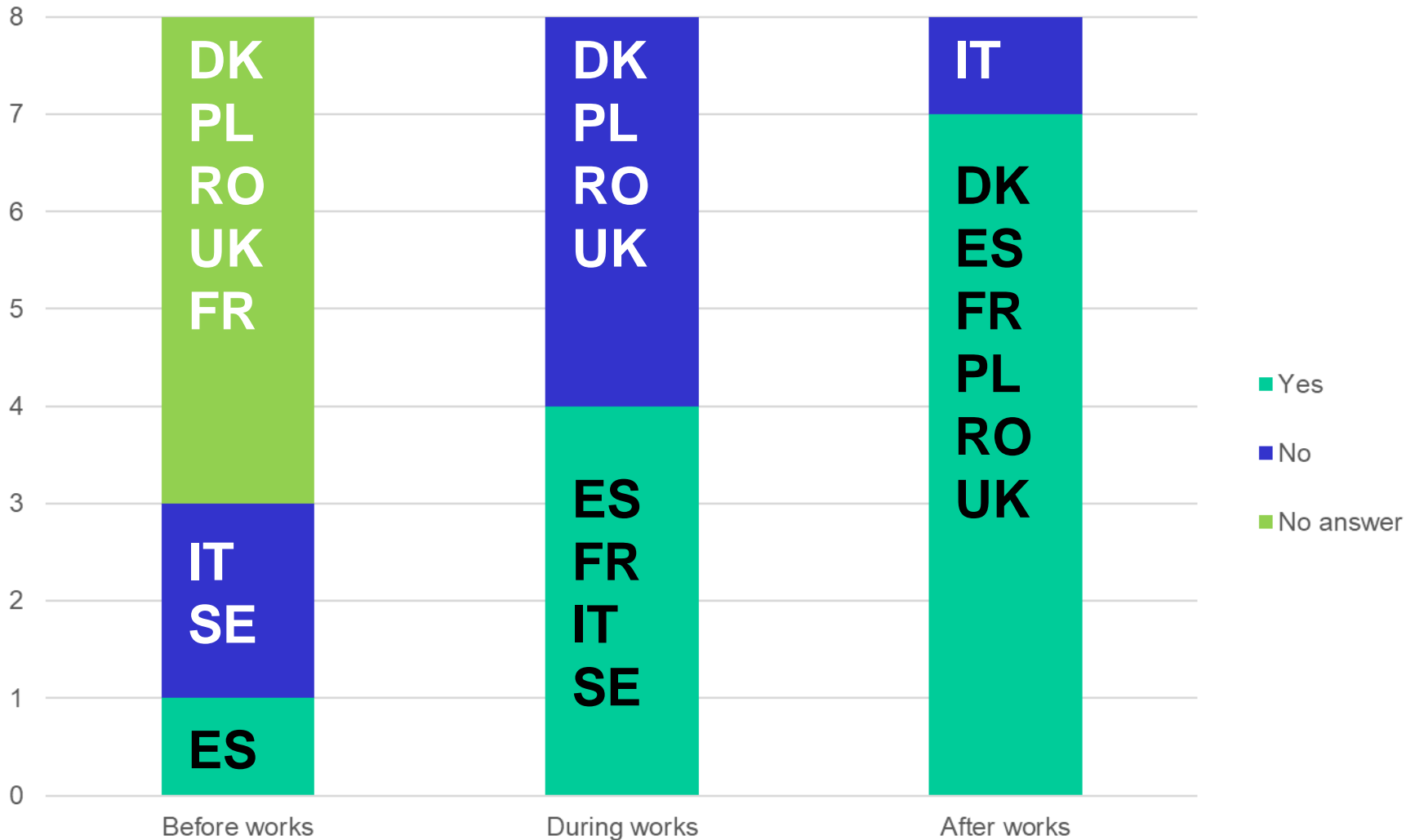
**In the case of renovations on site or in the vicinity, are particle/microbial air samplings recommended:**

	<b>Before works</b>	<b>During works</b>	<b>After works</b>
AT			P
DE			P
DK			PM
ES	PM	PM	PM
FR		PM	PM
IT		M	P
NL			P
PL			PM
RO			PM
SE		M	M
UK			PM

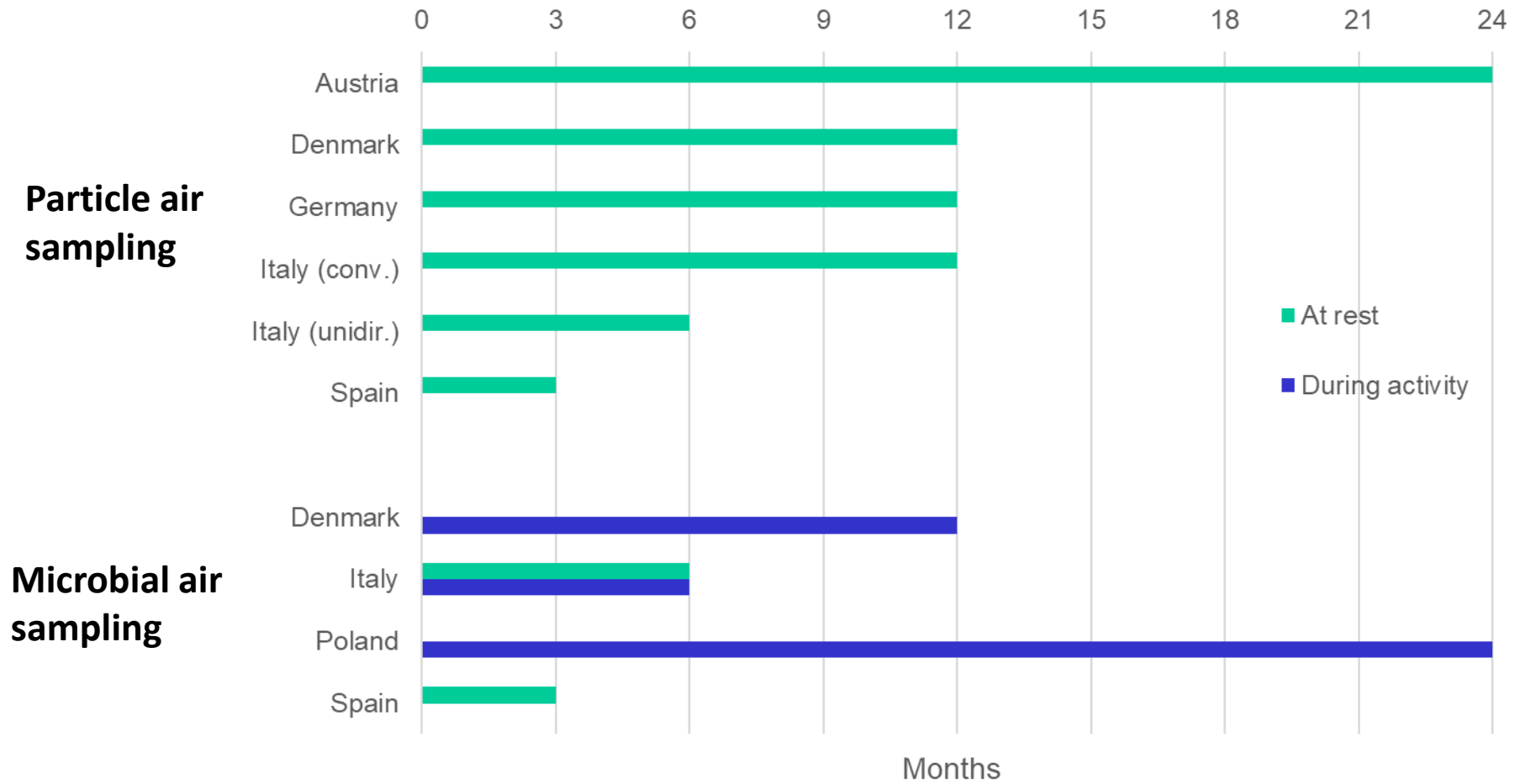
# In the case of renovations on site or in the vicinity, are particle air samplings recommended:



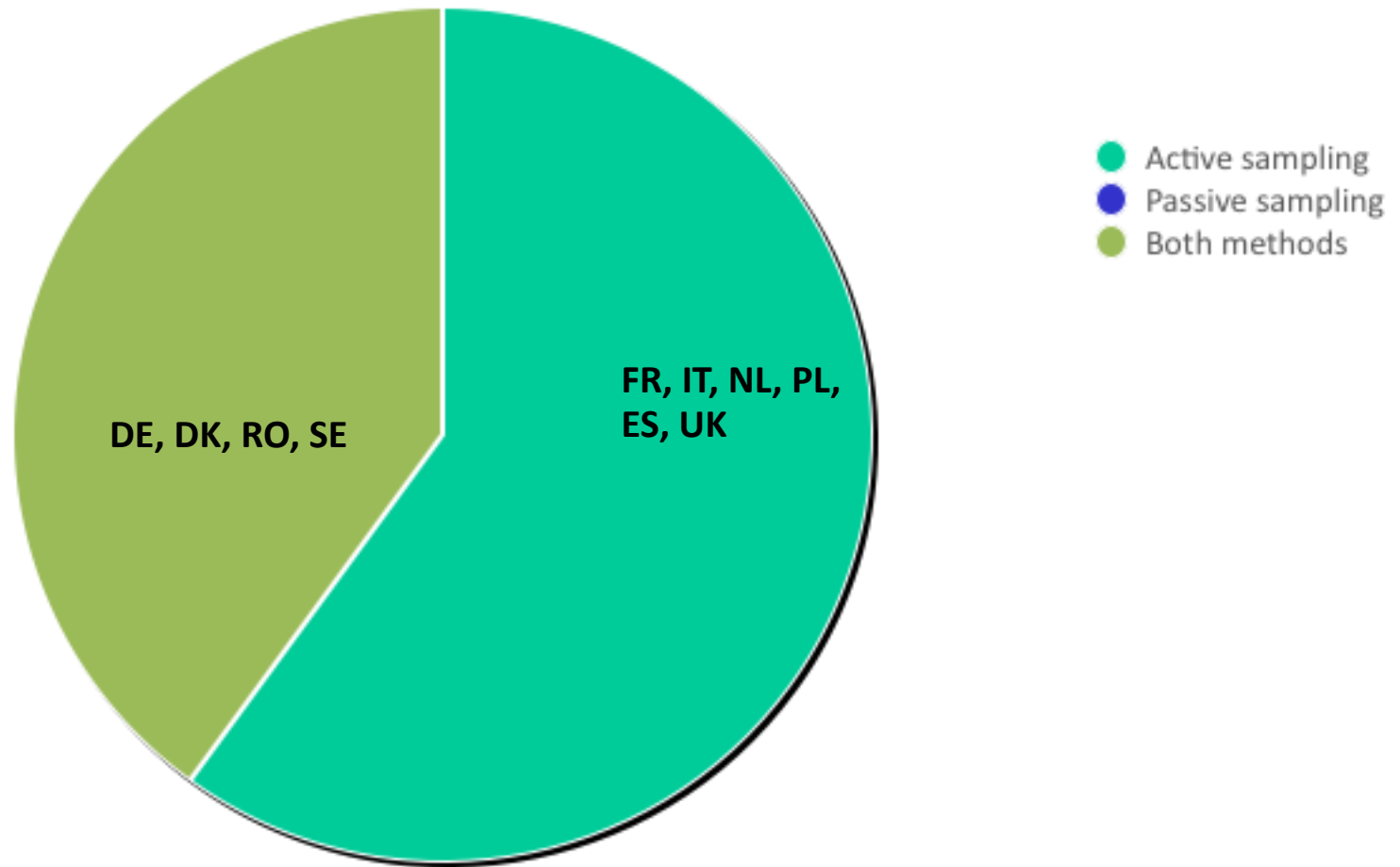
# In the case of renovations on site or in the vicinity, are microbial air samplings recommended:



**If a specific periodicity of particle/microbial air sampling for “at rest” or “during the surgical activity” is indicated, please specify:**



# Which method/methods are recommended for air microbial sampling?





**Is the active sampling device to be used indicated?**

**Is volume to be sampled indicated?**

**Are the sampling points indicated?**

<b>Country</b>	<b>Device</b>	<b>Volume</b>	<b>Points</b>
<b>Denmark</b>	Slit sampler	10 minutes with flow 1 m <sup>3</sup> /10 min * 3-4 / operation	30 cm from wound and at the edge of the instrument table
<b>France</b>	No	1m <sup>3</sup>	3 points in a diagonal centered on the wound
<b>Germany</b>			<i>No answer</i>
<b>Italy</b>	No	At least 1 m <sup>3</sup>	At rest: Center of the room, 1.5 m above the floor. Operational: Within 1m from the wound, 1m above the floor.
<b>Netherlands</b>			<i>No answer</i>
<b>Poland</b>	Slit and sieve impactors	1 m <sup>3</sup>	Yes
<b>Romania</b>			<i>No answer</i>
<b>Spain</b>	Impactors	1 m <sup>3</sup> per sample	At the inbound, in the middle of the room
<b>Sweden</b>	Impactation (Sieve sampler) or filtration (Sartorius MD8)	0.5 or 1 m <sup>3</sup> /10 min 5 times in a row during surgery	1.2 m above the floor at < 0.5 m distance to the operating site (the wound)
<b>UK</b>	No but generally slit used	No	Not specifically, grid format generally used

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**Is the size of settle plates indicated?**

**Is sampling time indicated?**

**Is settle plate height indicated?**

**Are the sampling points indicated?**

<b>Country</b>	<b>Plate size</b>	<b>Time</b>	<b>Height</b>	<b>Points</b>
<b>Denmark</b>	14 cm	No	No	In areas with high level of activity
<b>Germany</b>	25 cm <sup>2</sup>	-	-	-
<b>Romania</b>	10 cm	Yes, 10-15 min	Yes, 60-100 cm from the floor	Yes, in the middle of the room and in a corner of the room
<b>Sweden</b>	14 cm	1 hour	1.2 m above the floor	Since high air flow aggravates passive sedimentation, the settling plates should be placed in the periphery of the operating room

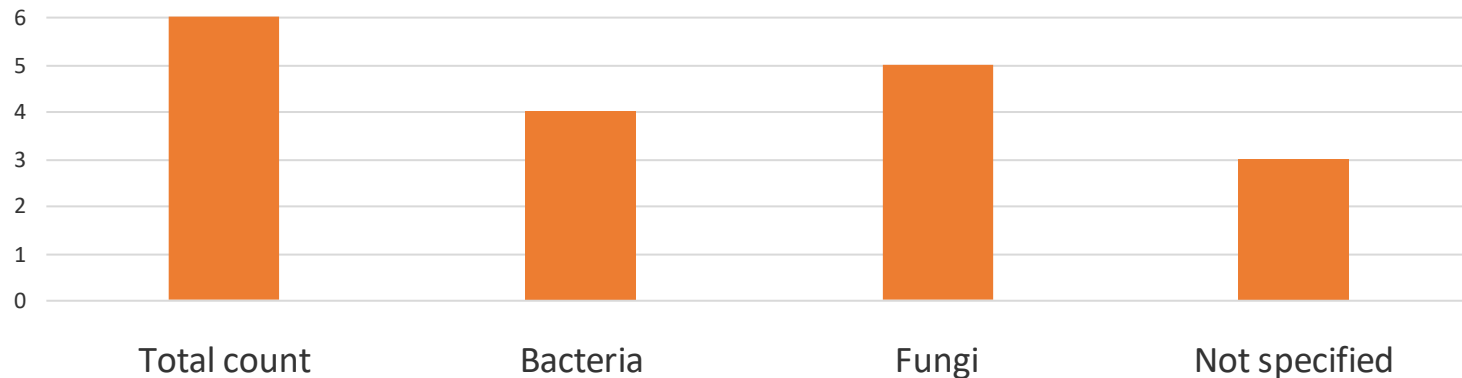
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## For the isolation of which infectious agents is sampling carried out?

	Total count	Bacteria	Fungi	Viruses	Other
DE					
DK	√				
ES			√		
FR	√	√	√		
IT	√	√	√		
NL					
PL	√				
RO	√	√	√		
SE	√	√	√		
UK					

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# For the isolation of which infectious agents is sampling carried out?



***If sampling is carried out for the isolation of bacteria and/or fungi, please specify genera/species:***

**France:** No recommendation but Staphylococci, Aspergillus may be considered

**Italy:** Guidelines do not explicitly state to isolate any species; however, they specify that target values are only valid in the absence of pathogen species (i.e. *S. aureus*, Gram-negative bacilli, *A. fumigatus* and *A. niger*) thus implying a search for those species should be performed.

**Romania:** Haemolytic colonies (legal requirement)

**Spain:** Filamentous fungi

**Sweden:** CoNS, *S. aureus*, moulds

# Which culture media are recommended for bacteria/fungi sampling?

Are the incubation time and temperature indicated for each culture medium?

*If yes, please report the culture medium, incubation time and temperature for bacteria/fungi*

Country	Bacteria media	Fungi media	Bacteria T° , time	Fungi T° , time
Romania	Agar and Blood agar	Not specified	On blood agar 24 h, on agar 48 h, at 37C	Not specified
Spain		Sabouraud		
Sweden	40 mL blood agar or 40 mL Tryptose Soy Agar (TSA)	Same	2 days incubation time at 35° C ±2° C for all plates	Same

# Do the guidelines/recommendations/official rules provide threshold values for microbial air contamination in «at rest» condition / during surgical activity?

*If yes, please specify the threshold values and the site for which that threshold value is recommended*

	AT REST		DURING ACTIVITY	
	Conventional	Unidirectional	Conventional	Unidirectional
DE	4 CFU/m <sup>3</sup> : target value; 10 CFU/m <sup>3</sup> : alert value		X	X
DK	X	X	100 CFU/m <sup>3</sup> (type 3), 200 CFU/m <sup>3</sup> (type 2)	10 CFU/m <sup>3</sup>
ES	0.1 CFU/m <sup>3</sup> (high risk) 10 CFU/m <sup>3</sup> (medium risk)	X	X	X
FR	10 CFU/m <sup>3</sup> (class 3)	10 CFU/m <sup>3</sup> (class 3), 1 CFU/m <sup>3</sup> (class 4)	X	X
IT	35 CFU/m <sup>3</sup>	X	180 CFU/m <sup>3</sup>	20 CFU/m <sup>3</sup>
NL	X	X	X	X
PL	✓ (no value provided)	✓ (no value provided)	10/20/70 CFU/m <sup>3</sup> <sup>(1)</sup>	X
RO	X	X	300 CFU/m <sup>3</sup>	X
SE	X	X	General surgery: 50-100 CFU/m <sup>3</sup> , 15-30 CFU/plate. Infection-prone surgery: 5-10 CFU/m <sup>3</sup>	
UK	10 CFU/m <sup>3</sup>	X	180 CFU/m <sup>3</sup>	10 CFU/m <sup>3</sup>

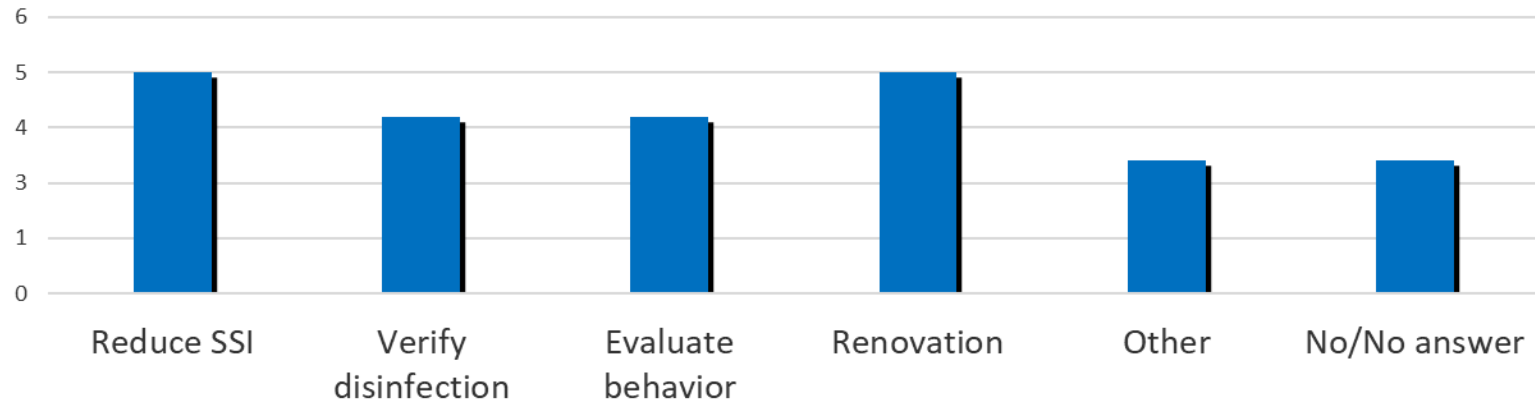
PL: (1) According to sampling point and OR class

**Is the aim of the microbial air sampling indicated? If yes, which of the following is/are indicated?**

	<b>Reduce SSI</b>	<b>Verify cleaning/ disinfection</b>	<b>Evaluate operators behavior</b>	<b>Evaluate prevention interventions during renovation activities</b>	<b>Other</b>
<b>AT</b>			<b>No</b>		
<b>DE</b>					√
<b>DK</b>	√		√	√	
<b>ES</b>	√	√			
<b>FR</b>					√
<b>IT</b>		√	√	√	√
<b>NL</b>			<b>No answer</b>		
<b>PL</b>	√	√		√	
<b>RO</b>	√	√			
<b>SE</b>	√		√	√	√
<b>UK</b>			√	√	

# Is the aim of the microbial air sampling indicated?

*If yes, which of the following is/are indicated?*



## OTHER:

**France:** Verify quality of air

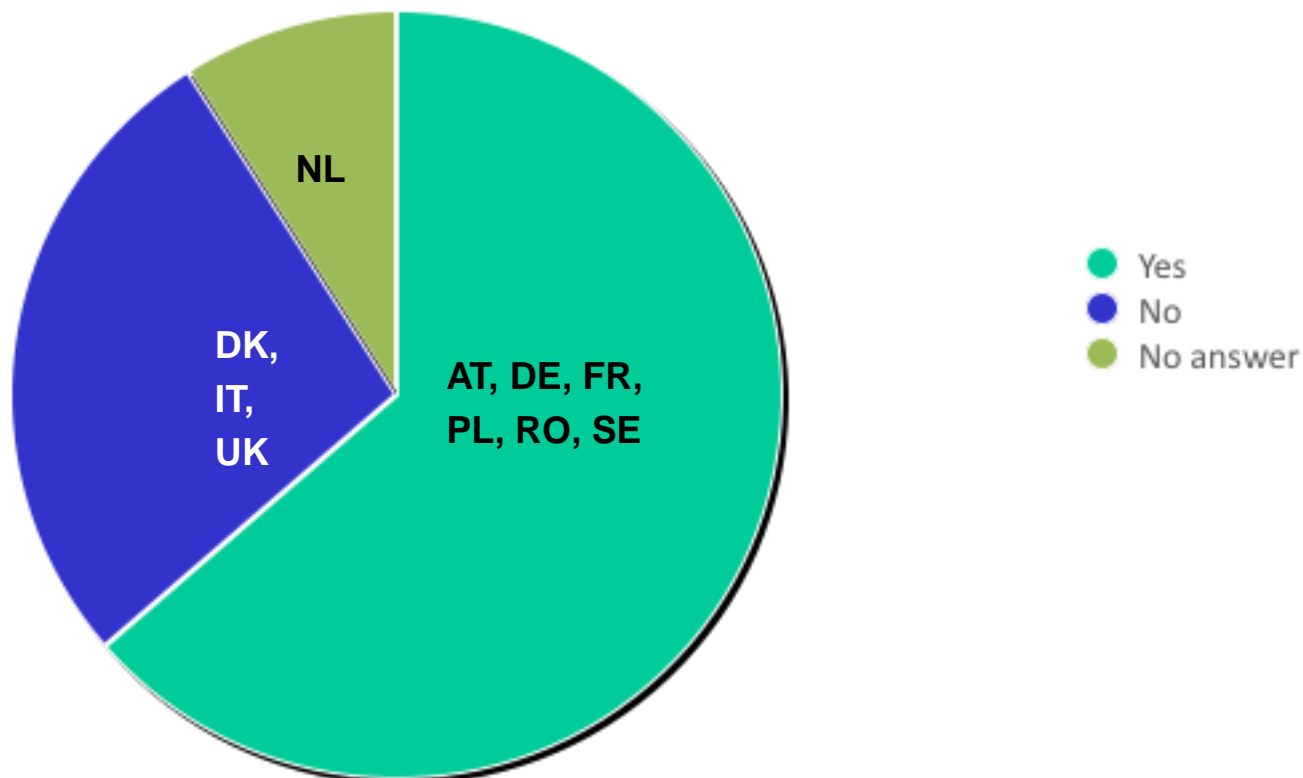
**Germany:** Test filter functioning

**Italy:** Evaluate the correct functioning of HVAC system, Assessment in case of epidemics

**Sweden:** Evaluate the capacity of the ventilation system, the clothing system and the number of people allowed to be present in the operating room during operations



## Is the feedback of the sampling results recommended?



## Are methods and times for returning the results indicated?

*If Yes, please specify:*

**Austria:** Yes, required by law. Sanitary authorities request measurements once / year

# Do the guidelines provide indication about who should carry out the microbial air sampling?

*If yes, please specify*

**France:** If indicated: trained personnel

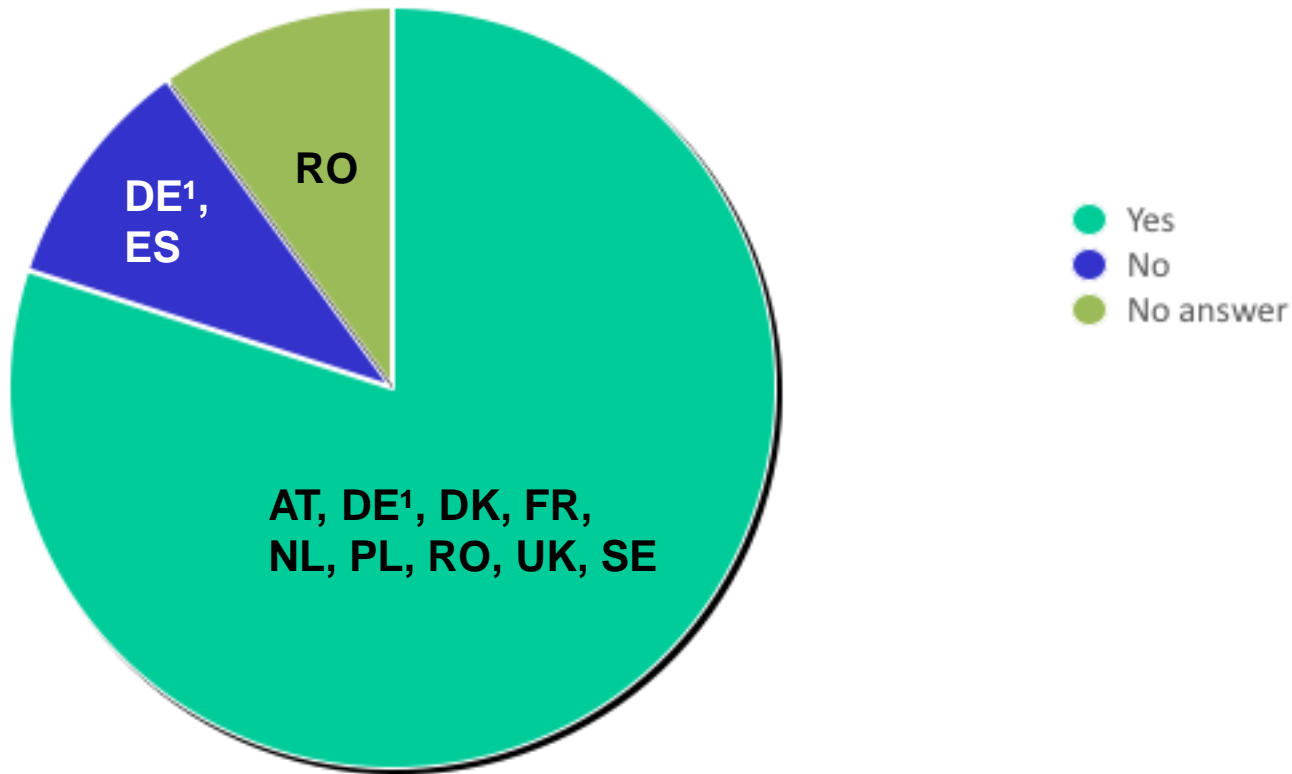
**Poland:** Infection control team

**Romania:** IC specialist, or Public Health Department

**Sweden:** A person with sufficient knowledge of the sampling method

**UK:** Authorised Engineers (ventilation)

# Is the use of unidirectional (laminar) airflow operating theaters recommended for hip and knee arthroplasty or other clean interventions?



1. Not recommended in DGHM guidelines, recommended in DIN guidelines.

## Some considerations

This survey has given a picture, at the European level, about the availability of indications on air quality in operating theatres

In a high percentage of respondent Countries “indications” are available

A wide variability in sampling methods, timing, periodicity, threshold values, has been highlighted which make a comparison of the results difficult

There is a need for a common standard, to be applied in order to verify that air quality in operating theatres is consistent with that specific kind of ventilation system

*It is truly confounding that rigorous air quality standards are applied to the drug and computer chip manufacturing industries, whereas the same rigor has not been embraced to provide a safe and effective operating theatre environment for surgical patients.*

*(Parvizi et al, 2017)*

Thanks to the Coordinator and all Members of the EUNETIPS for supporting this survey and to all the participant Countries for providing data.

**THANK YOU FOR YOUR ATTENTION**