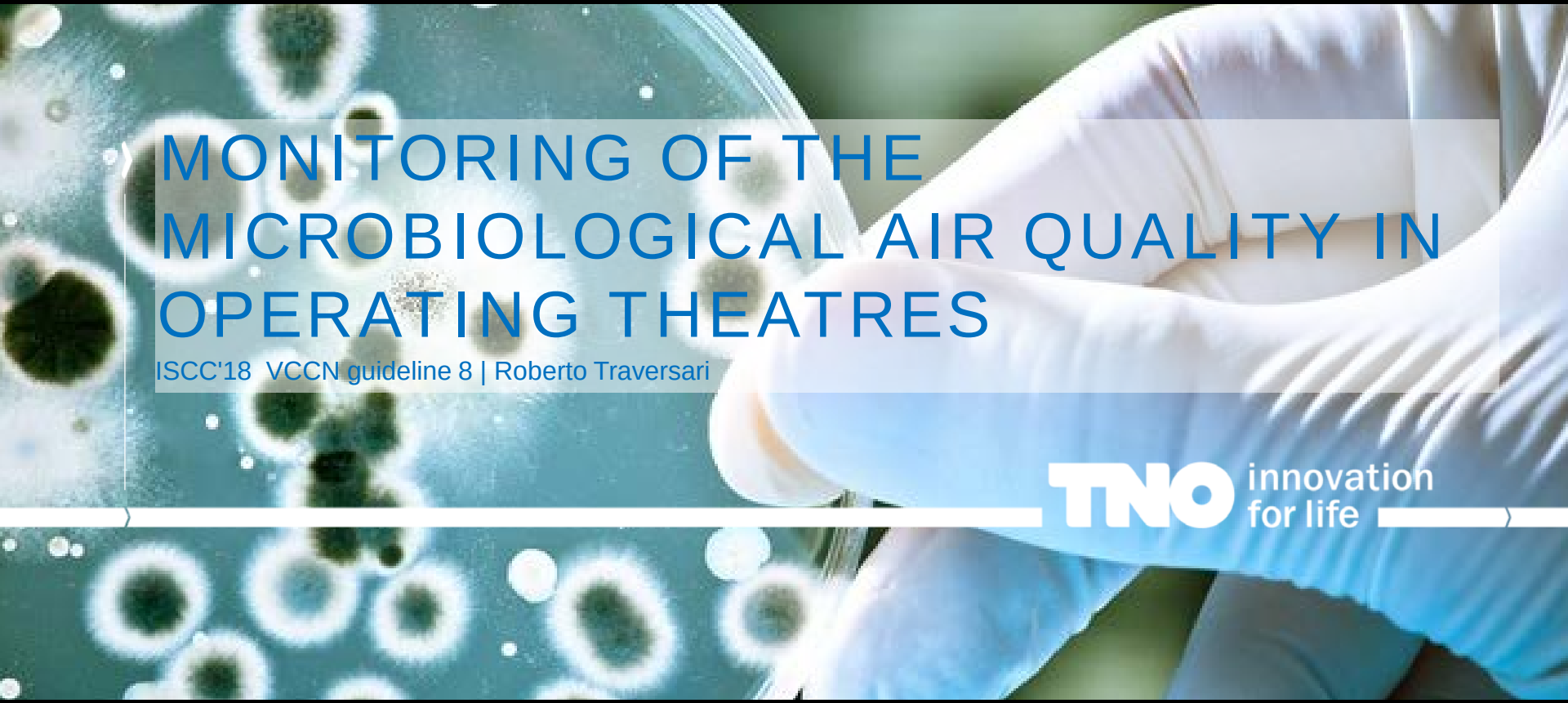

MONITORING OF THE MICROBIOLOGICAL AIR QUALITY IN OPERATING THEATRES

ISCC'18 VCCN guideline 8 | Roberto Traversari

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MONITORING OF THE MICROBIOLOGICAL AIR QUALITY IN OPERATING THEATRES

- Background and research related to CFUs
- Methodology of microbiological monitoring in operating theatres
- Experiences with CFU measurements in the Netherlands
- Possible threshold values

GOAL OF MICROBIOLOGICAL MONITORING DURING ONGOING SURGERY

- To prove that one is **IN CONTROL**
- Determine abnormalities related to a baseline
- Optimal alignment between technical and process-based measures

- In order to reduce as much as possible the “avoidable risks” (= reducing the chance of occurrence)

RISK IS

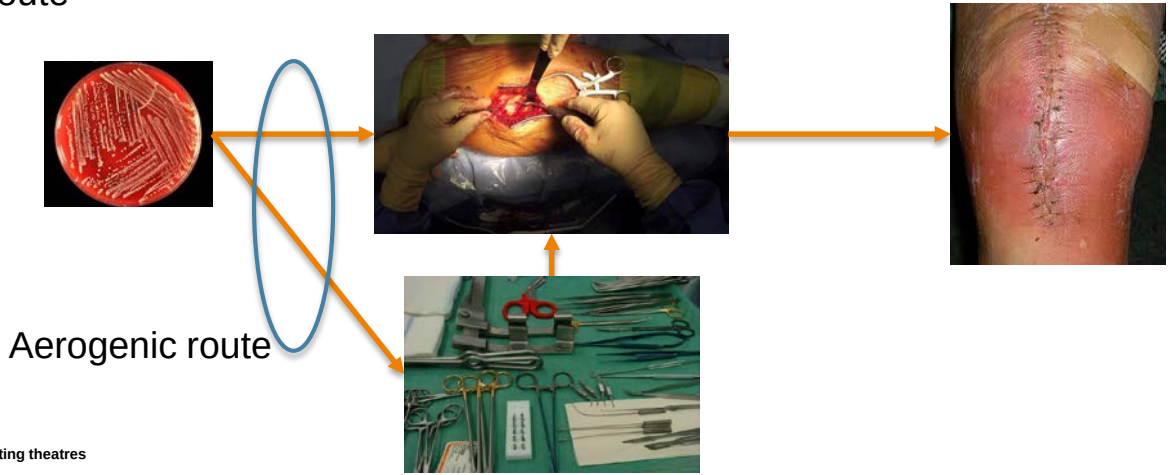
- Risk = **chance** of occurrence * **effect** of the occurrence

- Not all SSI are the same, some can be treated easily, some can have devastating affects on patients wellbeing

REDUCING THE CHANCE OF OCCURRENCE

- The less microorganisms carrying particles in the environment, the less the **chance** of contamination of the instruments and wound by the aerogenic route is

- The smaller the chance that a wound becomes infected, the smaller the chance that a (deep) infection will occur along this route



PROS AND CONS OF MICROBIOLOGICAL MONITORING

- Pros:
  - Outcome measure (CFU / m3) as "close as possible" to the clinical outcome measure SSI
  - Outcome measure is a result of technical and process oriented measures
  - Outcome measure gives more information about the actual probability of contamination of the wound or instruments than particle counts
  - Method could be used to demonstrate equal or better performance to guidelines and standards
- Cons:
  - Results are not immediately available
  - Method requires extensive efforts in the organization
  - Different measuring devices can give different results
  - Expertise is needed to perform the measurements adequately, and they shall be well-documented
  - Burden of proof for the threshold values is limited (Hoffman (2002), Whyte (1983), Lidwell et al (1983))

DOES MICROBIOLOGICAL MEASUREMENT AT REST MAKE SENSE?

- If the technical measurements (filters integrity, air flow, airflow direction etc.) indicate correct functioning of the system and proper cleaning has taken place, no microorganisms may be present in an empty operating room or instrument lay-up room.

- Are microorganisms measured then:
  - They probably come from the technician performing the measurements
  - Is the cleaning of the room performed very badly
  - There is a lot of air with microorganisms carrying particles entering the room
  - There is a big problem with the system

- This type of measurement is easy to perform, however, it doesn't give you information about the risk for the patient

CFU MEASUREMENT IS NOT NEW: THERE IS A LOT OF RESEARCH AVAILABLE

Some examples:

- The effect of "traffic" in the operating room
- The effect of door openings on UDF systems
- Relationship between wound contamination and SSIs
- Environmental quality indicators based on CFUs

THE EFFECT OF "TRAFFIC FLOW" IN THE OR

Andersson et al 2012, Traffic flow in the operating room: An explorative and descriptive study on air quality during orthopedic trauma implant surgery. American Journal of Infection Control 40 (2012) 750-5

Door openings are caused by consultation (6%), **supply of Instruments or other material needed** (26%), **change of personnel** (34%) and **social visits** (7%), and un-known reasons are responsible for 27% of the door openings.
14 out of 24 procedures > 10 KVE/m^3.
5 procedures > 25 KVE/m^3 highest average value 37.5 en 14.3 KVE/m^3

Traffic flow is a significant predictor of the CFU-level

Table 3
Reasons for traffic flow

Necessary door openings*	n	Semi-necessary door openings	n	Unnecessary door openings	n
Expert consultations (eg, help needed from senior surgeons, expert nurses, or anesthesiologists)	40	Surgical team members entering after incision or leaving before closure	76	Logistic reasons planning next or other operation	30
Instruments or other material needed	137	Lunch and coffee breaks	108	Social visits	45
				No detectable reasons	93
Total	177		184		168
					529

*The need assessed in relation to patient safety and ongoing procedure.

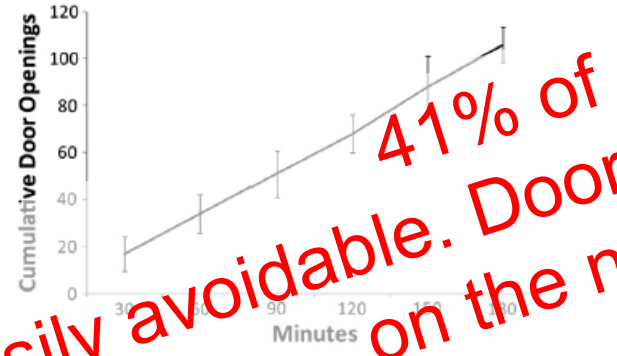
Table 2
Air quality and related variables

Variables	n (missing)	Mean (SD)	95% CI for mean	Median (range)
CFU/m^3	91 (1)*	15.9 (13.4)	13.1-18.7	13 (0-55)
Total CFU/m^3 per operation	24†	60.4 (55.9)	36.8-84	33.5 (7-187)
Number of people	111 (9)‡	5.4 (1)	5.2-5.6	5 (3-10)
Traffic flow rate	119 (1)‡	4.3 (2.9)	3.8-4.8	4 (0-14)
Traffic flow rate per operation	30†	17.4 (13.5)	12.4-22.4	14 (0-67)
Duration of surgery, minutes	29 (1)§	83.5 (39.7)	68.4-98.5	60 (20-200)

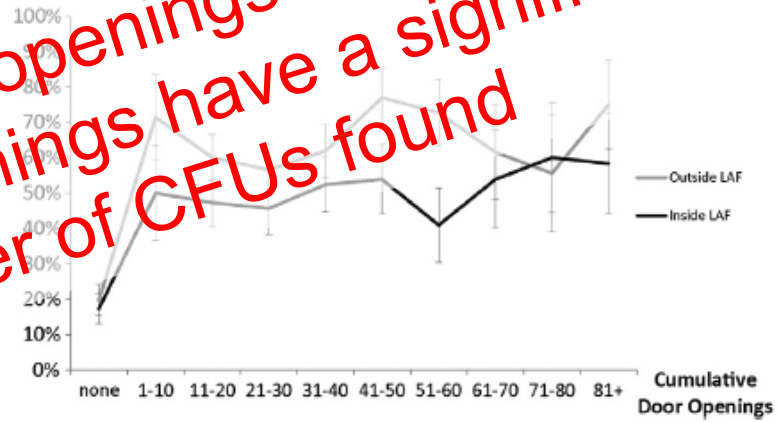
*Number of air samples.
†Number of operations.
‡Measured in 20-minute intervals.
§From incision time to end of closure in minutes.

EFFECT OF DOOR OPENINGS

Smith et al 2013, The Effect of Laminar Air Flow and Door Openings on Operating Room Contamination. The Journal of Arthroplasty 28 (2013) 1482–1485



Graph 2. Time vs. cumulative door openings, error bars ± 1 standard deviation.



Graph 3. Effect of cumulative door openings on contamination rate.

41% of door openings are easily avoidable. Door openings have a significant effect on the number of CFUs found

RELATION BETWEEN CFU/m³, PARTICLES AND WOUND CONTAMINATION

Birgand et al 2015, Air contamination for predicting wound contamination in clean surgery: A large multicenter study, American Journal of Infection Control 43 (2015) 516-251

In ORs with a diluting mixing system a correlation between particles and CFUs is found. A UDF system leads to lower CFU-levels in the air. A diluting mixing system leads to a higher degree of contamination of the wound.

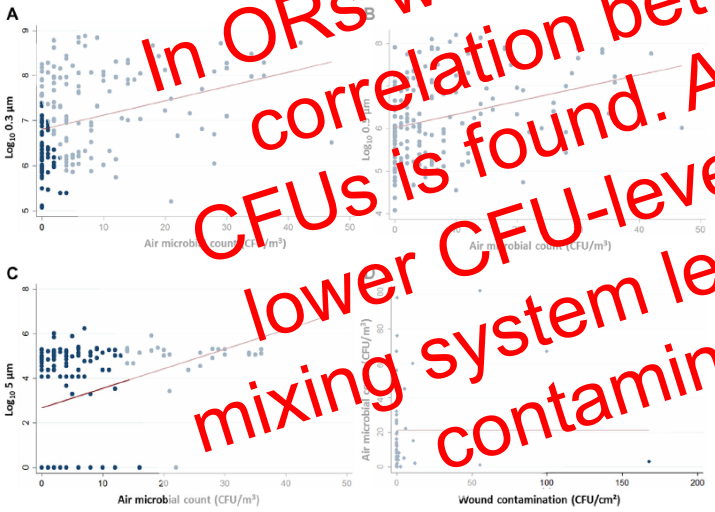


Fig 1. Distribution of particle counts according to air microbial counts [(A)–(C)] and air microbial counts according to wound contamination at closure (D). *CFU*, colony forming units.

Table 2

Variable			
Time 1: Incision			
Air microbiologic sampling	5 (0-9)	2.5 (0-6)	11 (2-20)
0	16 (26.7)	12 (35.3)	4 (7.7)
1-10	30 (50)	21 (61.8)	9 (17.3)
>10	14 (23.3)		
Log_{10} of 0.3 µm	7.8 (7.5-8.2)		8.3)
Log_{10} of 0.5 µm	7.9 (7.6-8.2)		7.8)
Log_{10} of 5 µm	4.8 (3.6-5.2)		5.3)
Time 2: Wound closure			
Air microbiologic sampling	3 (0-7.5)	1.5 (0-4)	5 (2-18)
0	17 (28.3)	15	2 (7.7)
1-10	31 (51.7)		13 (50)
>10			11 (42.3)
Log_{10} of 0.3 µm		6.5 (6.1-7.1)	7.6 (6.9-8.2)
Log_{10} of 0.5 µm		5.6 (5.2-6.1)	7 (6.1-7.3)
Log_{10} of 5 µm	4.4 (3.6-5.2)	4.4 (0-5)	4.6 (0-5.2)
Time 3: Wound closure			
Air microbiologic sampling	4 (0-9)	2 (0-5)	9 (3-17)
0	17 (28.3)	12 (35.3)	5 (19.2)
1-10	29 (48.3)	20 (58.8)	9 (34.6)
>10	14 (23.3)	2 (5.9)	12 (46.2)
Log_{10} of 0.3 µm	6.3 (6-7)	6.2 (5.9-6.5)	6.6 (6.1-7.1)
Log_{10} of 0.5 µm	5.5 (5.2-6.1)	5.4 (5.1-5.9)	6 (5.2-6.3)
Log_{10} of 5 µm	4.1 (0-5)	4.1 (0-4.9)	4.2 (0-5)
Total			
Air microbiologic sampling	4 (0-9)	2 (0-5)	8.5 (2-20)
0	50 (27.8)	39 (38.2)	11 (14.1)
1-10	90 (50)	59 (57.8)	31 (39.7)
>10	40 (22.2)	4 (3.9)	36 (46.2)
Log_{10} of 0.3 µm	7 (6.2-7.9)	6.5 (6.1-7.3)	7.4 (6.8-8.1)
Log_{10} of 0.5 µm	6.1 (5.4-7)	5.9 (5.2-6.7)	6.6 (6-7.3)
Log_{10} of 5 µm	4.6 (0-5.2)	4.5 (0-5)	4.8 (0-5.2)
Wound culture, CFU/cm²	0 (0-0.6)	0 (0-3)	0.3 (0-6.1)
0	33 (55)	24 (70.6)	9 (34.6)
1-10	21 (35)	10 (29.4)	11 (42.3)
>10	6 (10)	0	6 (23.1)

NOTE. Values are n (%), median (interquartile range), or as otherwise indicated.
CFU, colony forming units.

RELATION CFU <-> PARTICLES AND CFU -> SSI

Rabih et al 2017, Association of Airborne Microorganisms in the Operating Room With Implant Infections: A Randomized Controlled Trial. Infection Control & Hospital epidemiology 38 (2017) 4-10

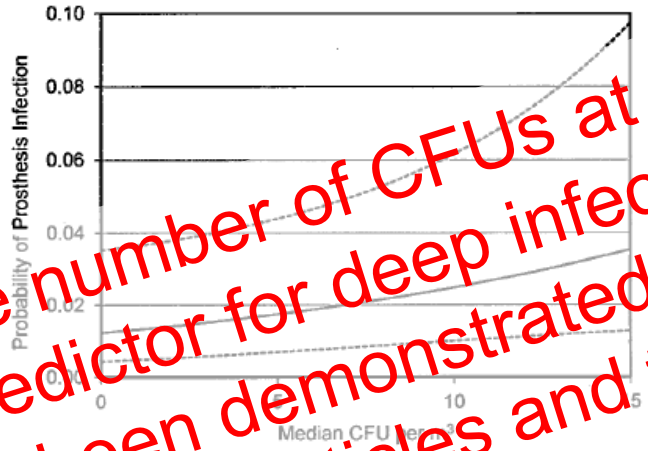


FIGURE 4. Graph of density of colony-forming units (CFU) at incision sites and probability of implant infection ($P = .021$). Dashed lines represent 95% CIs.

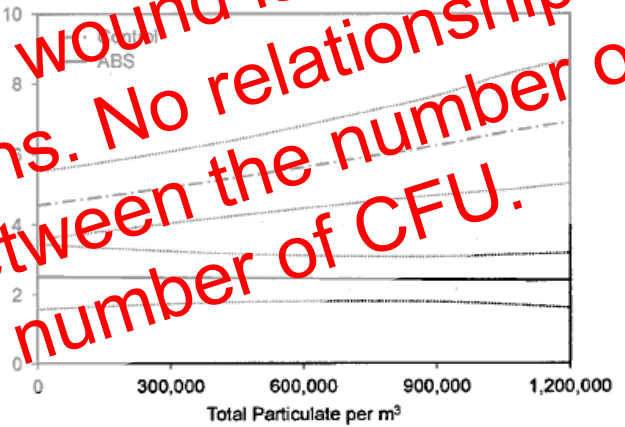


FIGURE 5. Graph of particulate density and colony-forming units (CFU). Dotted lines represent 95% CIs. ABS, Air Barrier System.

The number of CFUs at the wound is a significant predictor for deep infections. No relationship has been demonstrated between the number of particles and the number of CFU.


Methodology

VCCN GUIDELINE N8 – CFU MEASUREMENTS -

- Based on SIS TS:39 ““Microbiological cleanliness in the operating room – Preventing airborne contamination – Guidance and fundamental requirements”

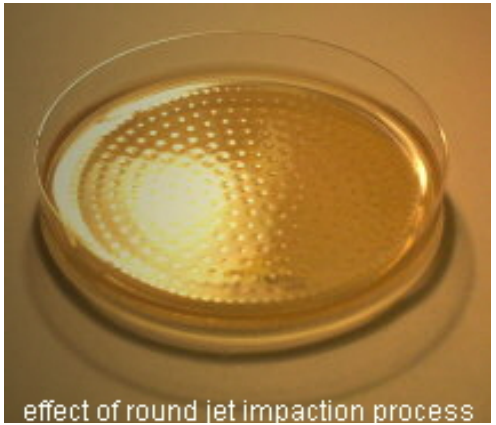
RL-8 VERSUS SIS-TS39:2015

Aspect	RL-8	SIS-TS39:2015
Air flow sampling	*50 -* 100 dm^3/min	100 dm^3/min (recommended)
Volume sample	0,5 - 1 m^3 (10 min)	1 m^3 (10 min)
Measuring position	< 50 cm from the surgical wound, *10-15 cm is recommended*	< 50 cm from the surgical wound and instrument table
Maximal lenght sampling tube	*3 m**	-
Samples	At least 5 surgical procedures in the same OR, 3 samples (start incision, in the middle of surgical time, 10 minutes before closing)	At least 5 surgical procedures in the same OR, *Surgical procedure (insicion to closure) > 45 min*, 3-4 samples /operation
Cultivation plates	TSA/Blood agar** (2 days aerobically at 35 °C ± 2 °C)	TSA/Blood agar (2 days aerobically at 35 °C ± 2 °C)
Requirements acticve sampler	According EN-ISO 14698	D_{50} for 2,0 µm particles according to EN-ISO 14698 (50% counting efficiency for ≥ 2,0 µm particles)

** effect of sampling tube < 20%, Whyte et al. Suggested bacteriological standards for air in ultraclean operating rooms. Journal of Hospital Infection (1983) 4, 133-139*
***blood agar is not advised because this type of cultivation plate is too rich*

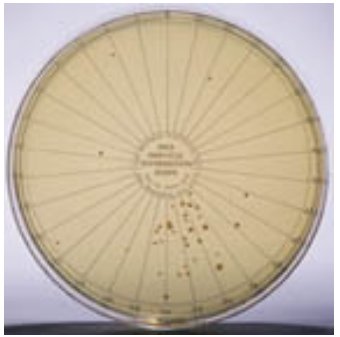
SAMPLER WITH IMPACTOR PRINCIPLE

- Impactor principle
- Easy to use
- Some models need an adaptor to connect a sampling tube



SLIT SAMPLERS

- Impactor principle
- Easy to use
- The time of impact of the micro-organism can be traced by the slow-rotating culture plate, specially suitable for research purposes
- Can sometimes also be used with a gelatin membrane filter



GELATIN MEMBRANE FILTER

- Gelatin membrane filter with a pore size of less than 3 µm
- Microorganisms are captured on the filter surface
- The gelatin membrane filter can be positioned close to the position of interest by use of a connection tube
- The gelatin membrane filter is placed on a culture plate
- Handling of the gelatin filter is critical, chance of undesirable contamination is high

PROCEDURE

- Measurements close to the surgical wound:
  - After the patient has been positioned and covered, the sterile sample tube is attached to the cover sheet by the scrub nurse at a distance of no more than 50 cm, preferably less, from the wound
  - Then the other end of the sample tube is given by the scrub nurse to the measurement technician and linked to the air sampler
  - The air sampler is activated at the moment of the incision, halfway the procedure or at a critical moment with regard to the air quality during the procedure and just before closure of the surgical wound
  - At least 3 samples are taken during the surgical procedure

RECORDING CIRCUMSTANCES

Date:		**Type air sampler and unique code:**
Type of procedure:		Type of culture plate:
Technician:		Sample number/code:
Start incision:	Closure:	Clothing system:

Nr.	Start time	End time	Number of door movements	Number of staff	Remarks during samplinhg	Remarks counting e.g. CFU or fungus	Number of CFU	Date counting CFUs
Reference plate								
Sample 1								
…….								
Average value								
Maximum value								
Remarks:								

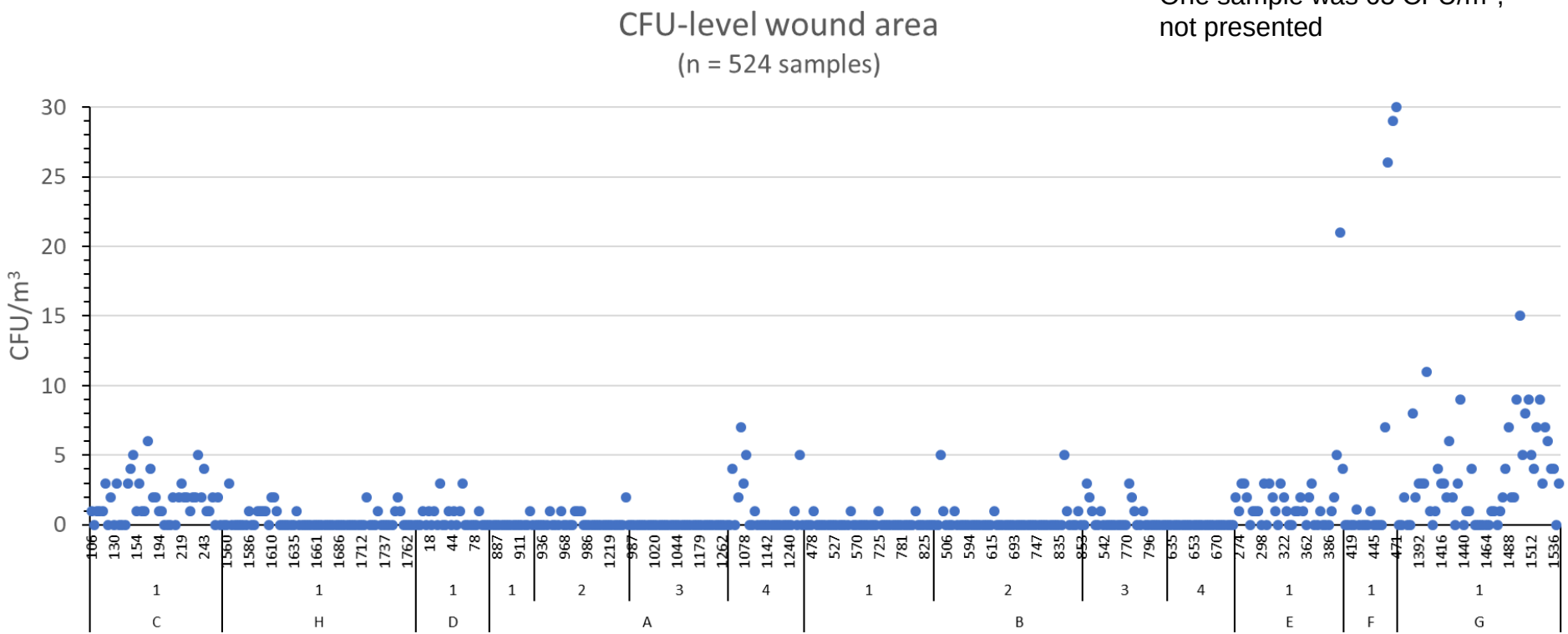
MANAGING MEASUREMENT DATA

- The results provide data for the own location, a base line can be established.
- High or deviated results are an indication for further research into possible causes.
- In case of an increase in the number of infections, the database can be consulted to find a possible cause.

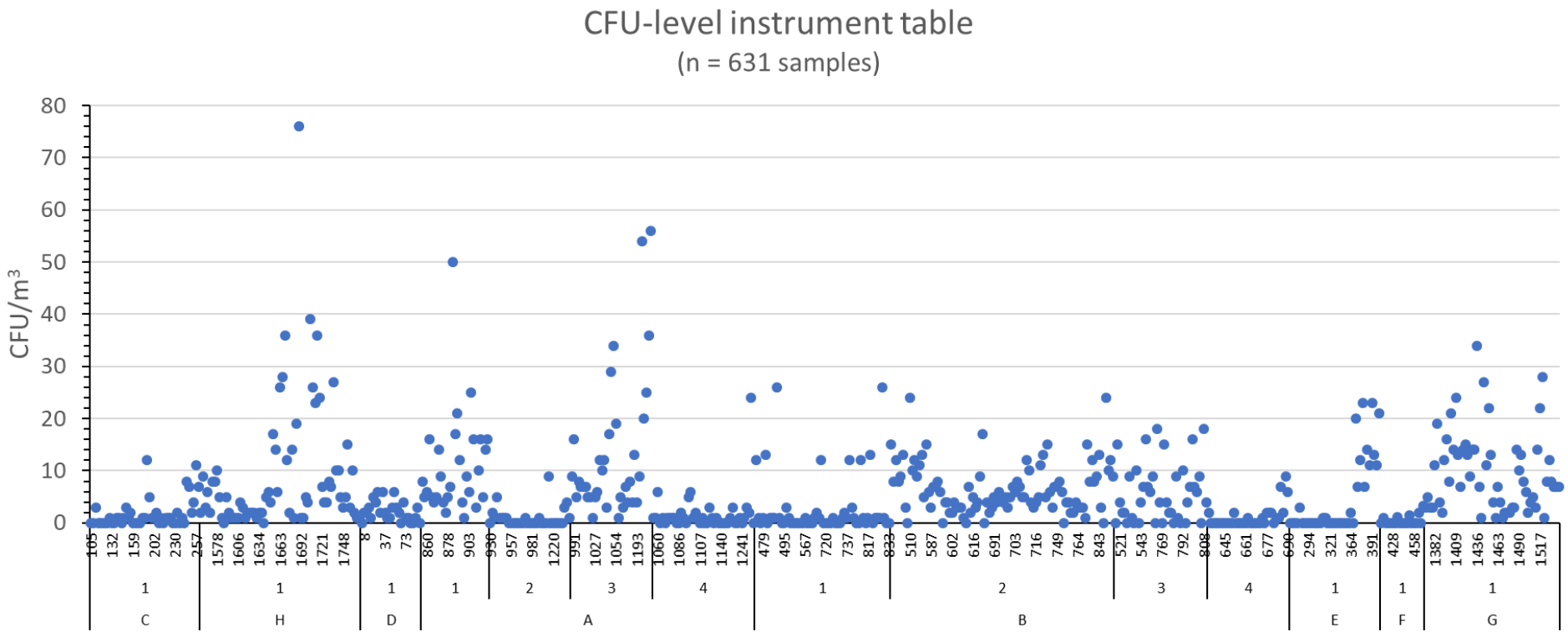

Experience

RESULTS WOUND AREA

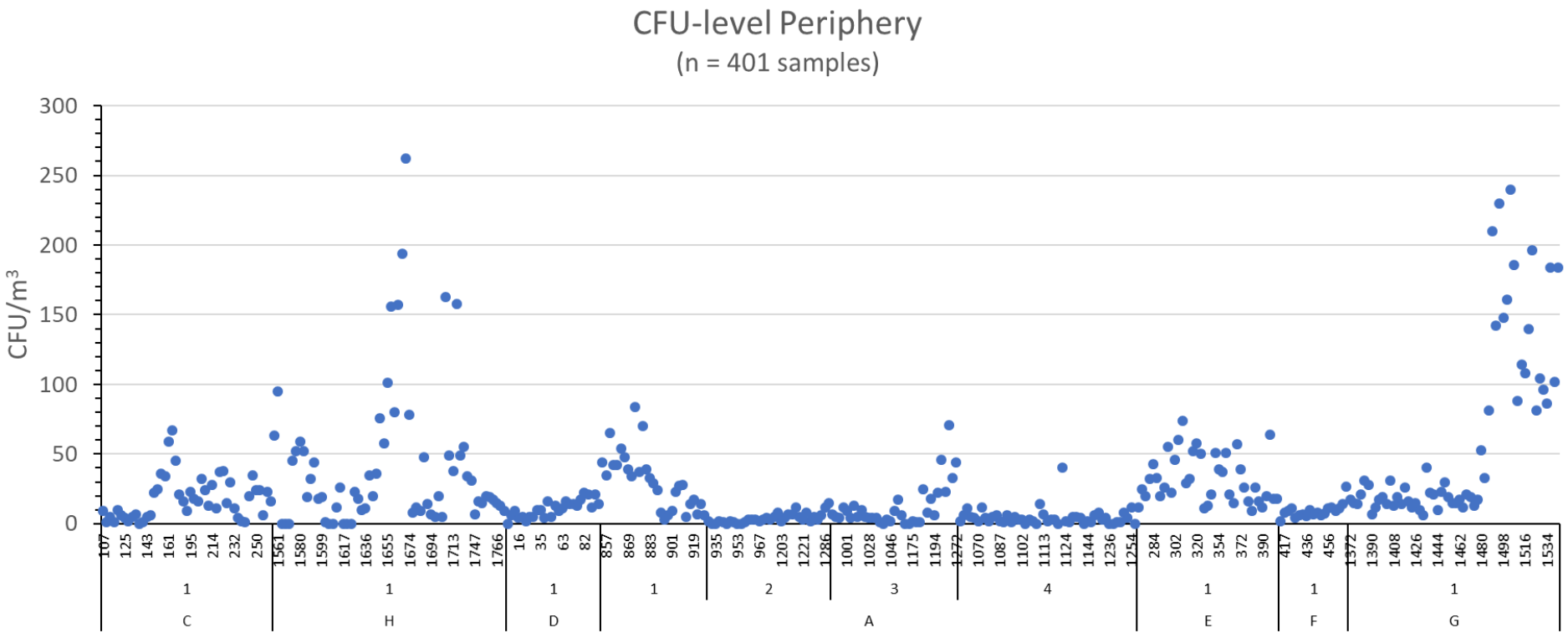
One sample was 65 CFU/m^3, not presented



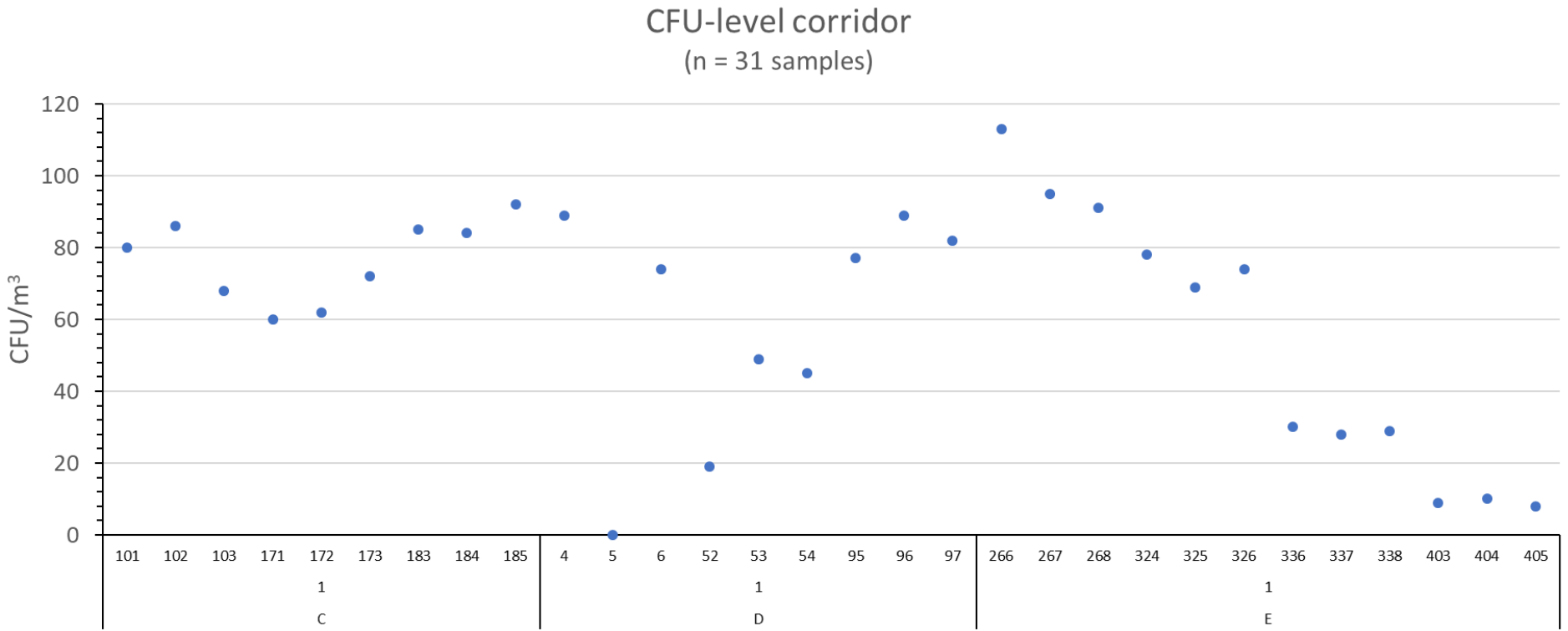
RESULTS NEAR THE INSTRUMENT TABLE



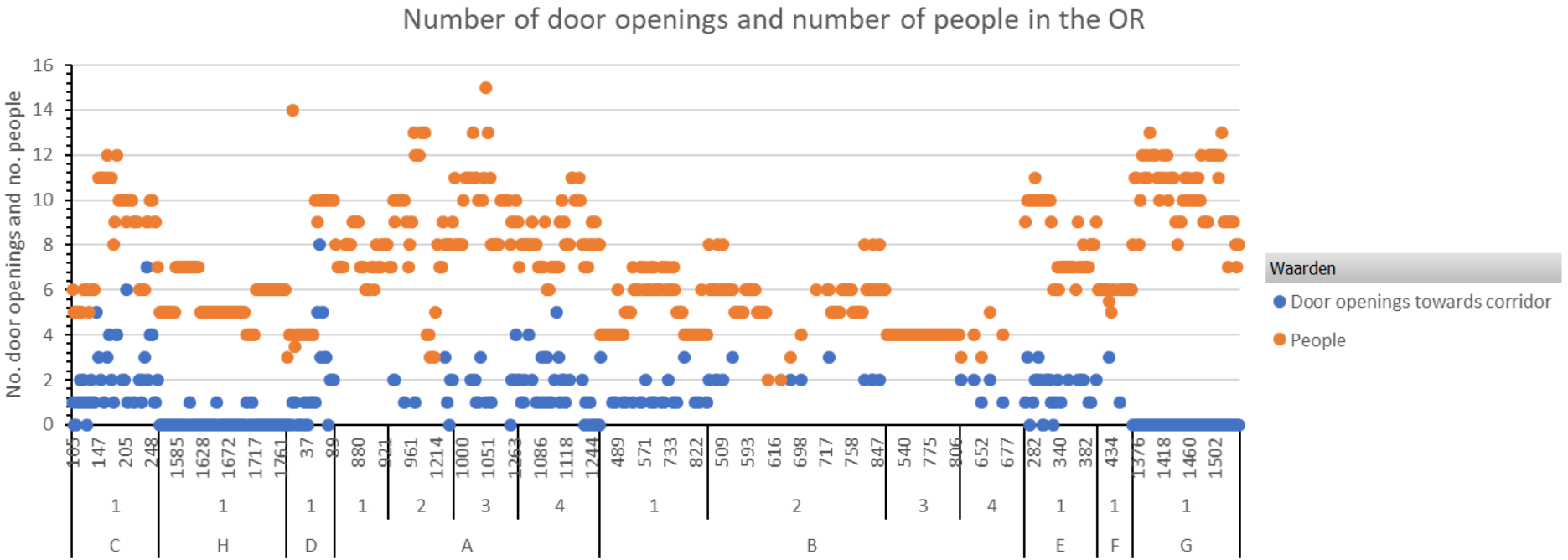
RESULTS PERIPHERY



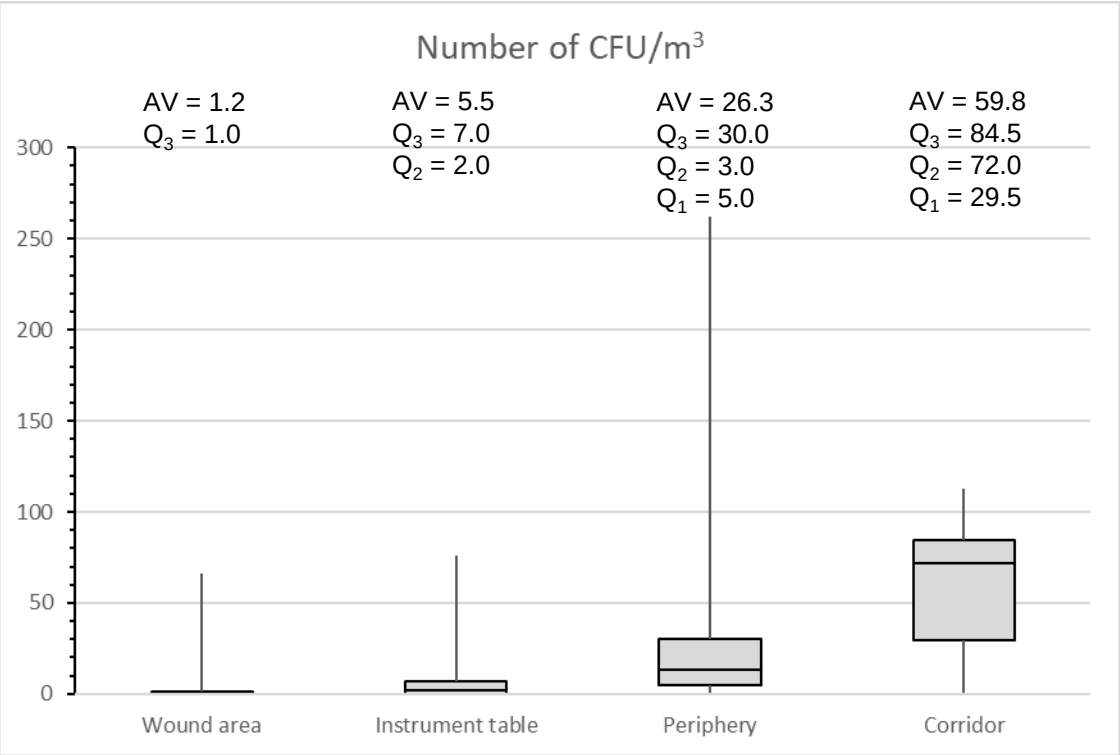
RESULTS CORRIDOR



ACTIVITY LEVEL

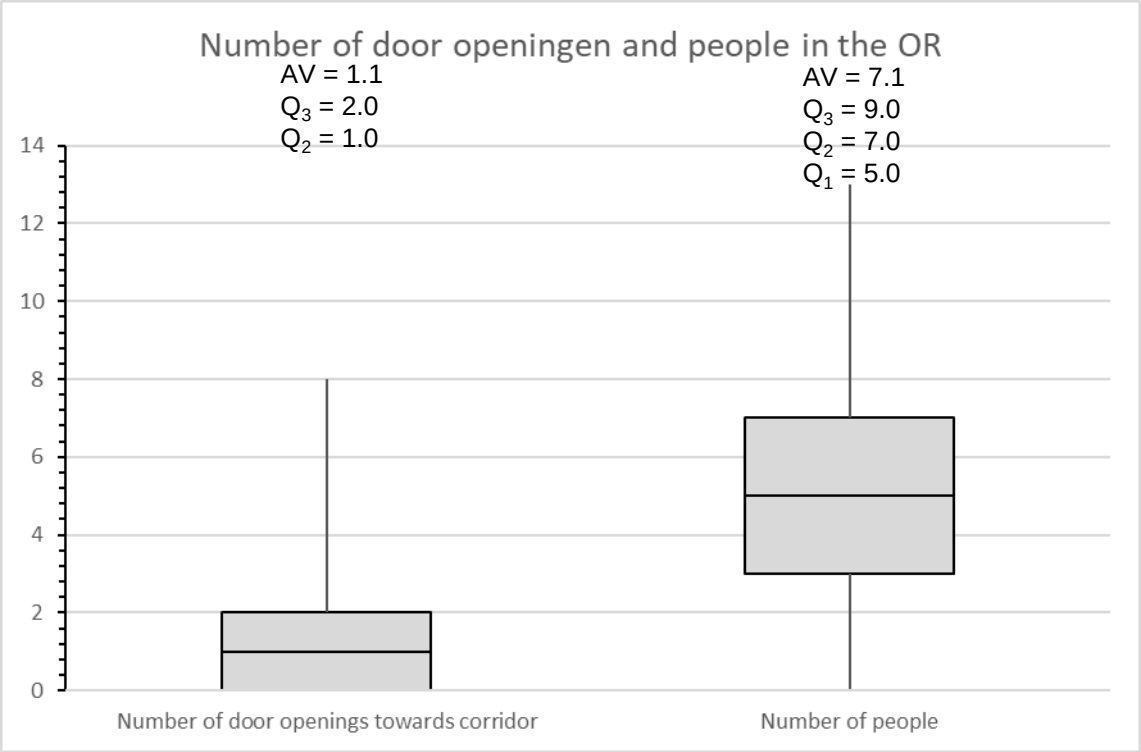


SUMMARY CFU-LEVELS



AV = Average
Q_3 = 75th percentile
Q_2 = 50th percentile (median)
Q_1 = 25th percentile

SUMMARY ACTIVITY LEVEL



AV = Average
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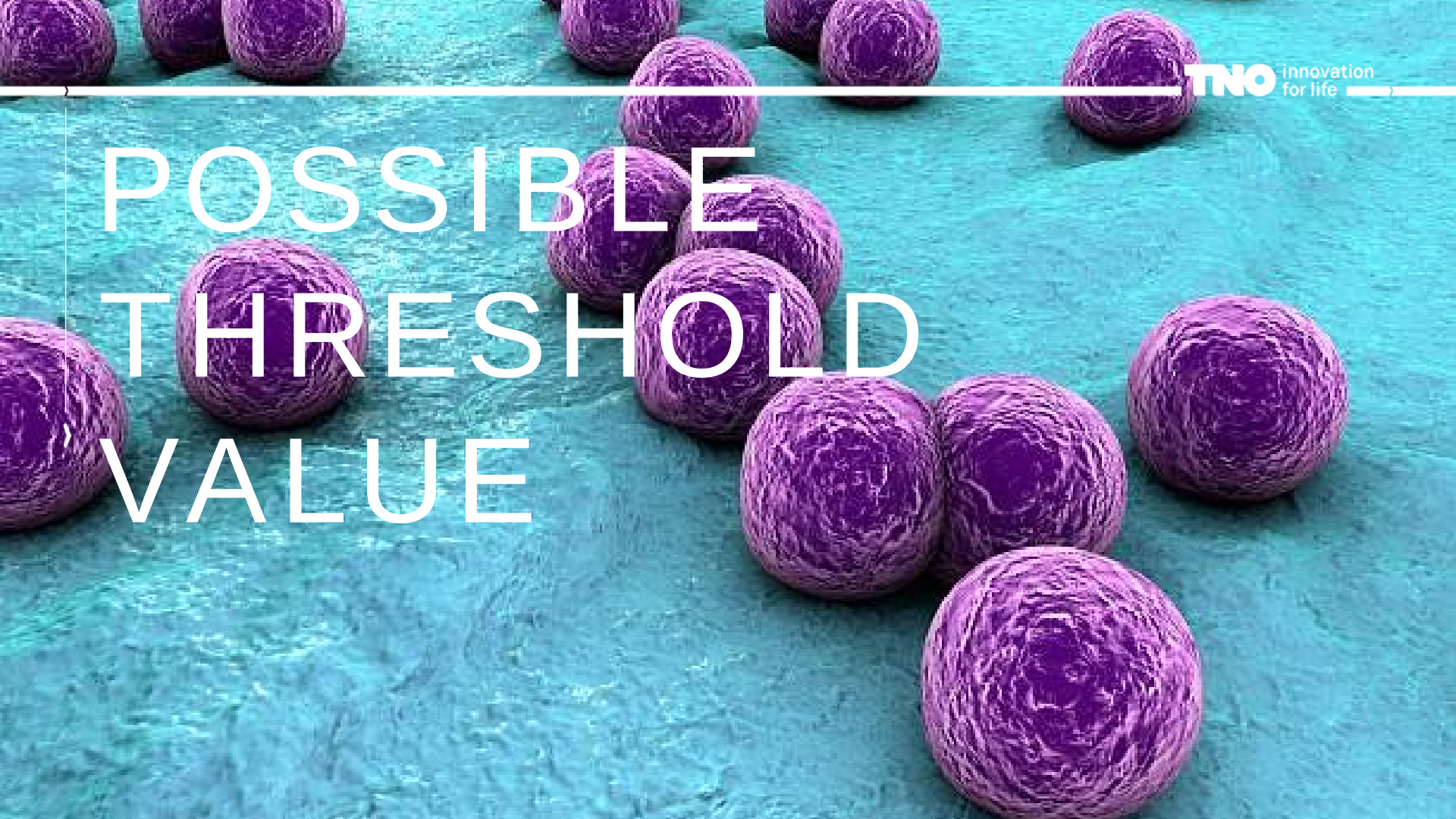
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POSSIBLE
THRESHOLD
VALUE

POSSIBLE THRESHOLD VALUES

- Hoffman et al. Microbiological commissioning and monitoring of operating theatre suites. Journal of Hospital Infection (2002) 52: 1-28. doi:10.1053/jhin.2002.1237
  - Less than 30 cm from the surgical wound < 10 KVE/m^3
  - At the edge of the clean zone < 20 KVE/m^3
- Whyte et al. Suggested bacteriological standards for air in ultraclean operating rooms. Journal of Hospital Infection (1983) 4, 133-139
  - < 10 KVE/m^3 Close to the wound during operation and < 20 KVE/m^3 In the remainder of the working area of the clean air system.
- Lidwell et al. Airborne contamination of wounds in joint replacement operations: the relationship to sepsis rates. J Hosp Infect 1983; 111-131.
  - < 10 KVE/m^3

MICROBIOLOGIC MEASUREMENTS ACCORDING TO SIS-TS39:2015

- Requirements:
  - **infection-prone clean surgery:** average value (<10 KVE/m^3 for normal clothing and (<5 KVE/m^3 for clean air suits), maximum value for individual samples should not exceed (30 KVE/m^3 respectively 15 KVE/m^3)
  - **Non-infection-prone clean surgery:** average value (<100 KVE/m^3 for normal clothing and (<50 KVE/m^3 for clean air suits), maximum value for individual samples should not exceed (200 KVE/m^3 respectively 100 KVE/m^3)

APPLICATION OF CFU MEASUREMENTS

- This type of measurements is performed after acceptance of the system by the client. Is not an acceptance test
- For training purposes (insight into the effects of adjustment in process and technique)
- Can be used if an increased infection level occurs
- Excellent method to show that you are in control and to optimize (technique and process!)
- Method for demonstrating that the taken measures are equivalent to guidelines and standards*

* *Traversari et al., Nederlands Tijdschrift voor Medische Microbiologie, 2017*

THANK YOU FOR YOUR ATTENTION

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