The Science of Operating Room Ventilation: How Well Does My Ventilation System Perform and Does it Really Matter?

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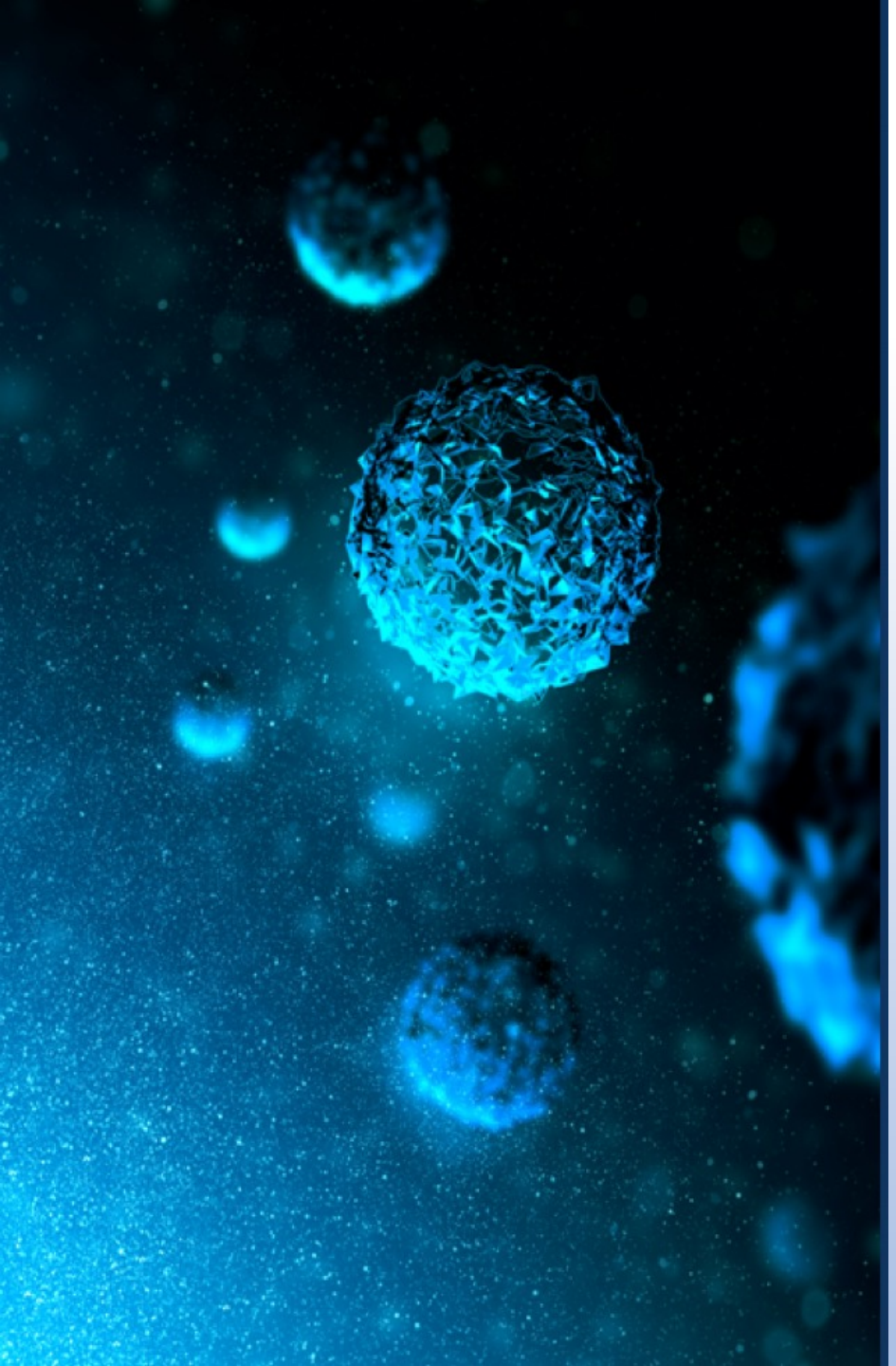
What we will learn today

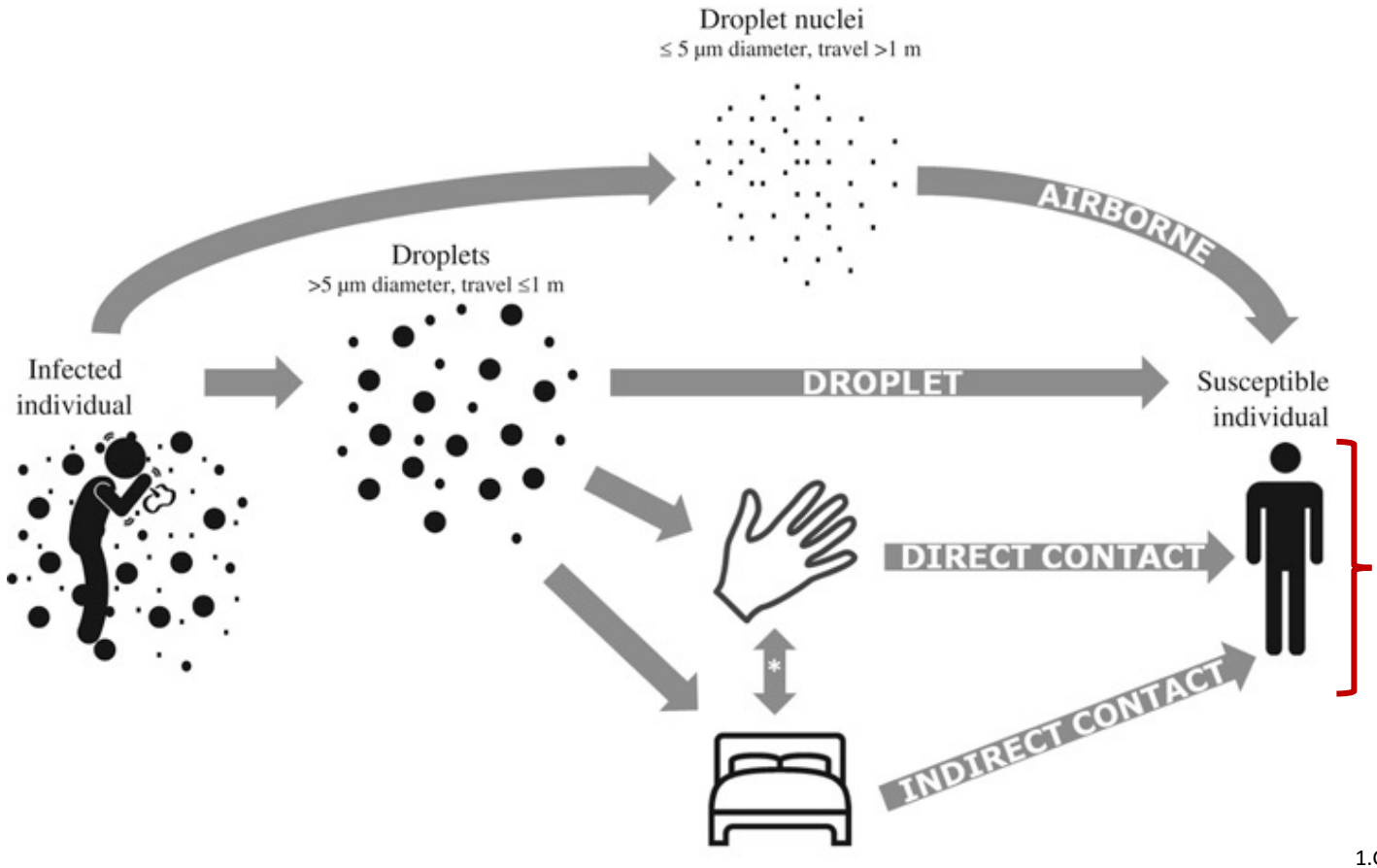
- Correlation of airborne microbial contamination and HAI/SSI
- Introduction to Temperature-controlled Air Flow (TcAF) ventilation
- How TMA, LAF and TcAF differ in terms of physics and engineering
- Comparative analysis of performance
- Evidence from UR Medicine *Orthopedics & Physical Performance Center* testing of new ORs



Correlation of Airborne Microbial Contamination and HAIs

Behavior of Airborne Pathogens: Routes of Transmission

Transmission routes: droplet, airborne, direct contact, and indirect contact.



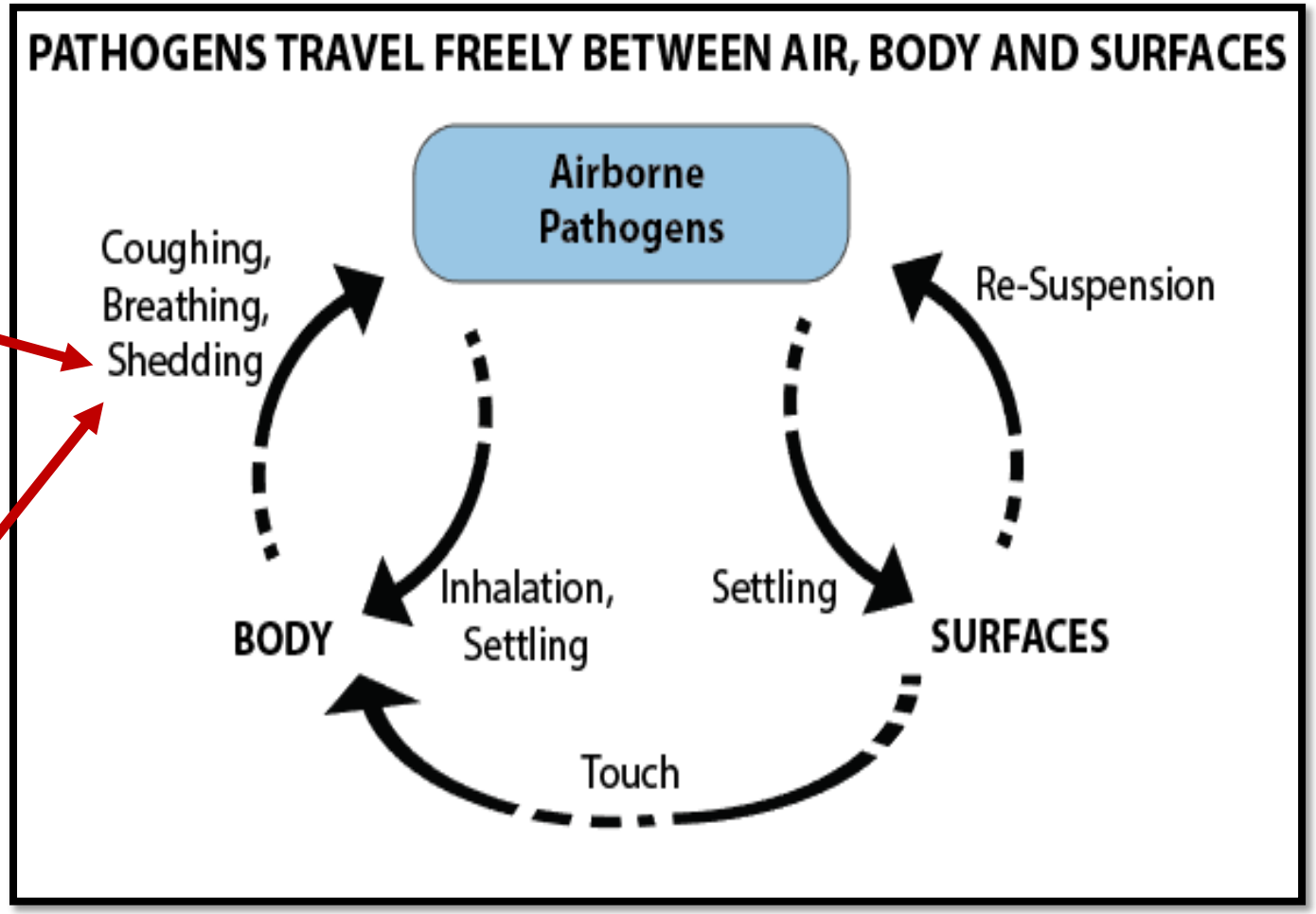
* Transmission routes involving a combination of hand & surface = indirect contact.

Particles carrying infectious microorganisms do not exclusively disperse by airborne or droplet transmission, but by both methods simultaneously.[1]

Aerosolized micro-droplets of certain pathogens, such as SARS-CoV2, can stay aloft for hours.[2]

1.Gralton J, Tovey E, McLaws ML, Rawlinson WD. The role of particle size in aerosolised pathogen transmission: a review. *Journal of Infection*. 2011;62(1):1–13.
2.Otter JA, et al. Transmission of SARS and MERS coronaviruses and influenza virus in healthcare settings: The possible role of dry surface contamination. *J Hosp Infect*. 2016;92(3):235-250.

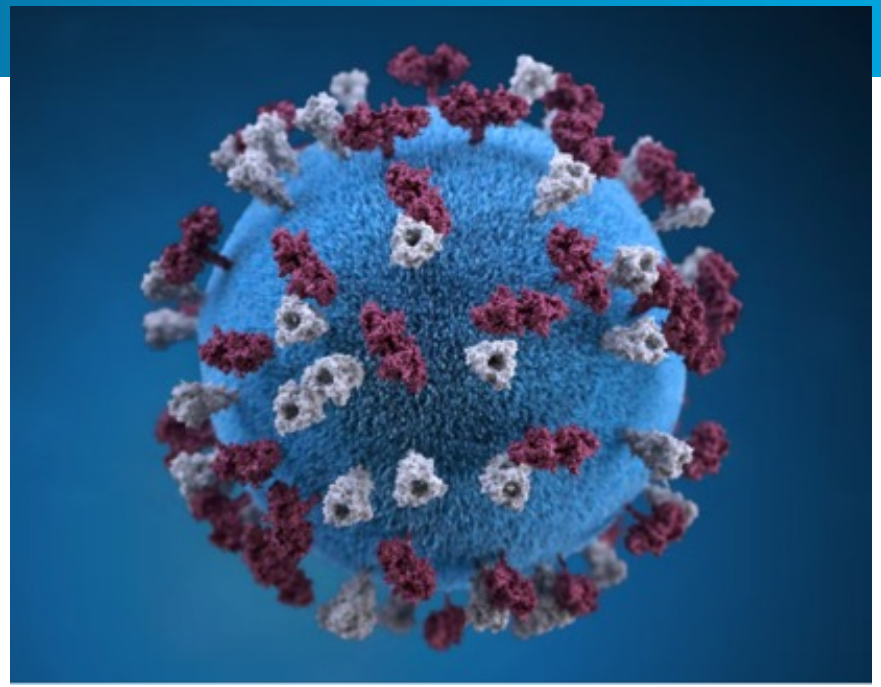
Behavior of Airborne Pathogens



- We *shed* about 10 million particles per day, and approximately 5–10% of these particles carry bacteria.
- Continual redistribution of microbes at the air, body, surface nexus.[1]
- Bacterial and fungal counts in air showed a significantly positive correlation with bacterial surface contamination.[2]

1. Ijaz, M. Khalid, et al. "Generic aspects of the airborne spread of human pathogens indoors and emerging air decontamination technologies." *American Journal of Infection Control* 44.9 (2016): S109-S120.
2.Luksamijarulkul P, Pipitsangjan S. Microbial air quality and bacterial surface contamination in ambulances during patient services. Oman Med J. 2015 Mar;30(2):104-10.

Airborne contamination: An *underappreciated* source of Healthcare-Associated Infection (HAI)



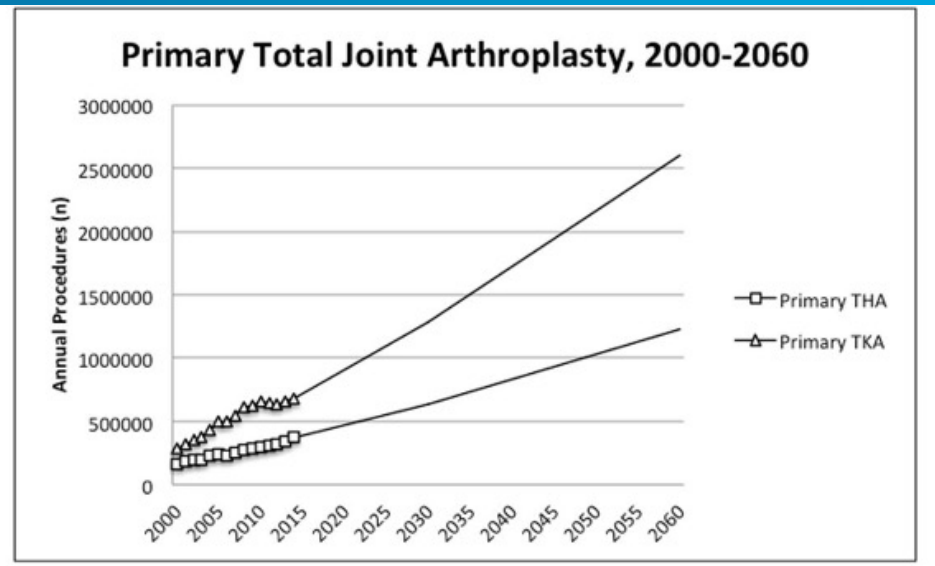
Peer-reviewed sources suggest, **10-16% of HAIs result directly** from airborne pathogen transmission and **up to 30% have airborne contribution**.

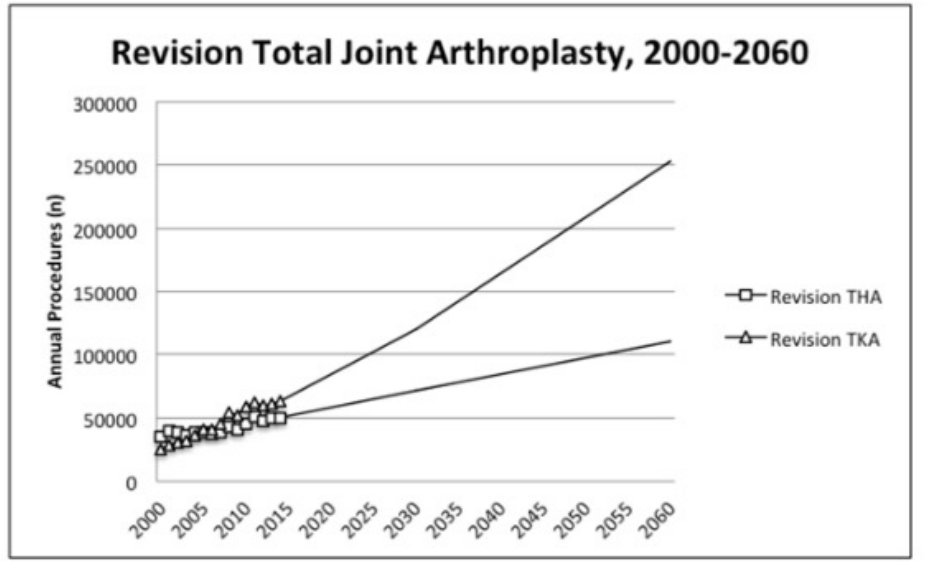
- Over 60 years of evidence supporting contribution of airborne microbial contamination to **Surgical Site Infection** (SSI). Kundsin: Airborne transmission accounts for 20%–24% of post operative wound infections.[1]
- Brachman: Airborne transmission responsible for 10%–20% of all *endemic* Hospital-Acquired Infections[2]
- Kowalski estimates approximately one-third of all HAIs involve airborne transmission at some point between the origin and the susceptible host[3].

1. R. B. Kundsin, "Documentation of airborne infection during surgery," Annals New York Academy of Sciences, vol. 353, pp. 255–261, 1980 1.
2. Brachman PS, "Hospital-acquired infection—airborne or not?" in Proceedings of the Int. Conf. on Hospital-Acquired Infections. 1971. Am Hospital Assn, Chicago, Ill, USA.
3. Kowalski W, Air-Treatment Systems for Controlling Hospital Acquired Infections, HPAC Engineering, Jan 2007

Prosthetic Joint Infection (PJI): On the Rise

- 2.18% of hip & knee arthroplasties become infected?[1] An *underestimate*!
- Average incremental costs with SSI are substantial, ranged from $14,298 to $29,176 for superficial incisional SSI and from $41,381 to $59,491 for deep incisional SSI[2].
- Rates of infection rising due to patient demographics and growing number of comorbidities.[3]
- PJI mortality rate - between 2–7%.[4]
- 5-year survival rate is worse than with many cancers.[4]
- Exponential growth in THA & TKA volume & revision. 2060 est: [5]
  - Primary THA: 1.23M (133%)
  - Primary TKA: 2.6M (382%)
  - ***Revision THA*:** 110,000 (219%)
  - ***Revision TKA***: 253,000 (400%)



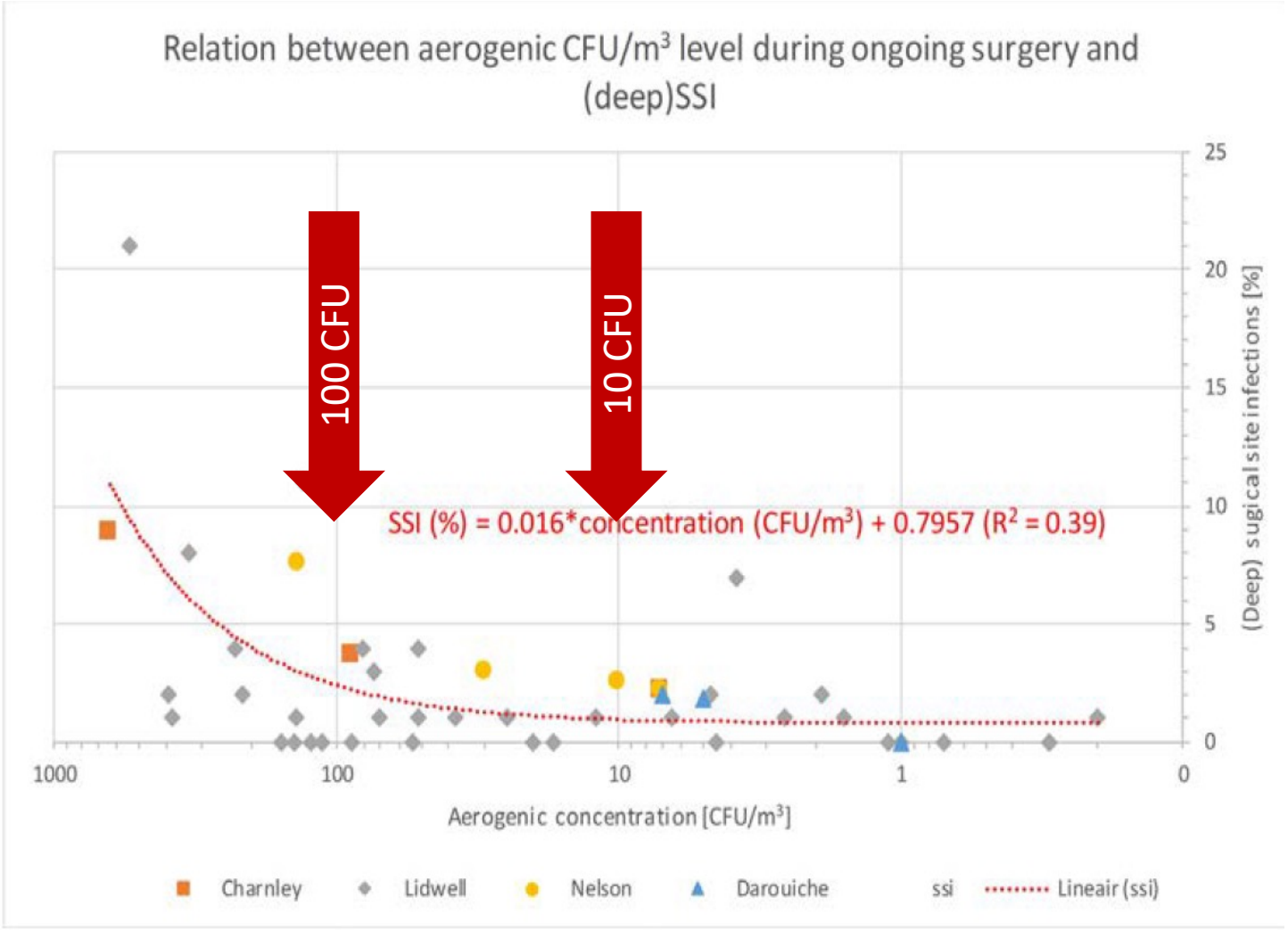


1. Kurtz SM. Economic burden of periprosthetic joint infection in the United States. J. Arthroplasty 2012.27:61–65.e61.
2. Edmiston CE Jr, et al. Longitudinal rates, risk factors and costs of superficial and deep incisional surgical-site infection (SSI) after primary and revision total knee arthroplasty: A US retrospective claims database analysis. Infect Control Hosp Epidemiol. 2023 Feb 2:1-9.
3. Edmiston Jr. CE, et al. Impact of patient comorbidities on surgical site infection within 90 days of primary and revision joint (hip and knee) replacement. Am J Infect Cont. 2019; 47 (10): 1225-1232.
4. Tande AJ, Patel R. Prosthetic Joint Infection. Clinical Microbiology Reviews. 2014;27(2):302-345. doi:10.1128/CMR.00111-13
5. Jeppe Lange, Chronic Periprosthetic Hip Joint Infection. A Retrospective, Observational Study on the Treatment Strategy and Prognosis in 130 Non-Selected Patients PLoS One.2016;11(9)

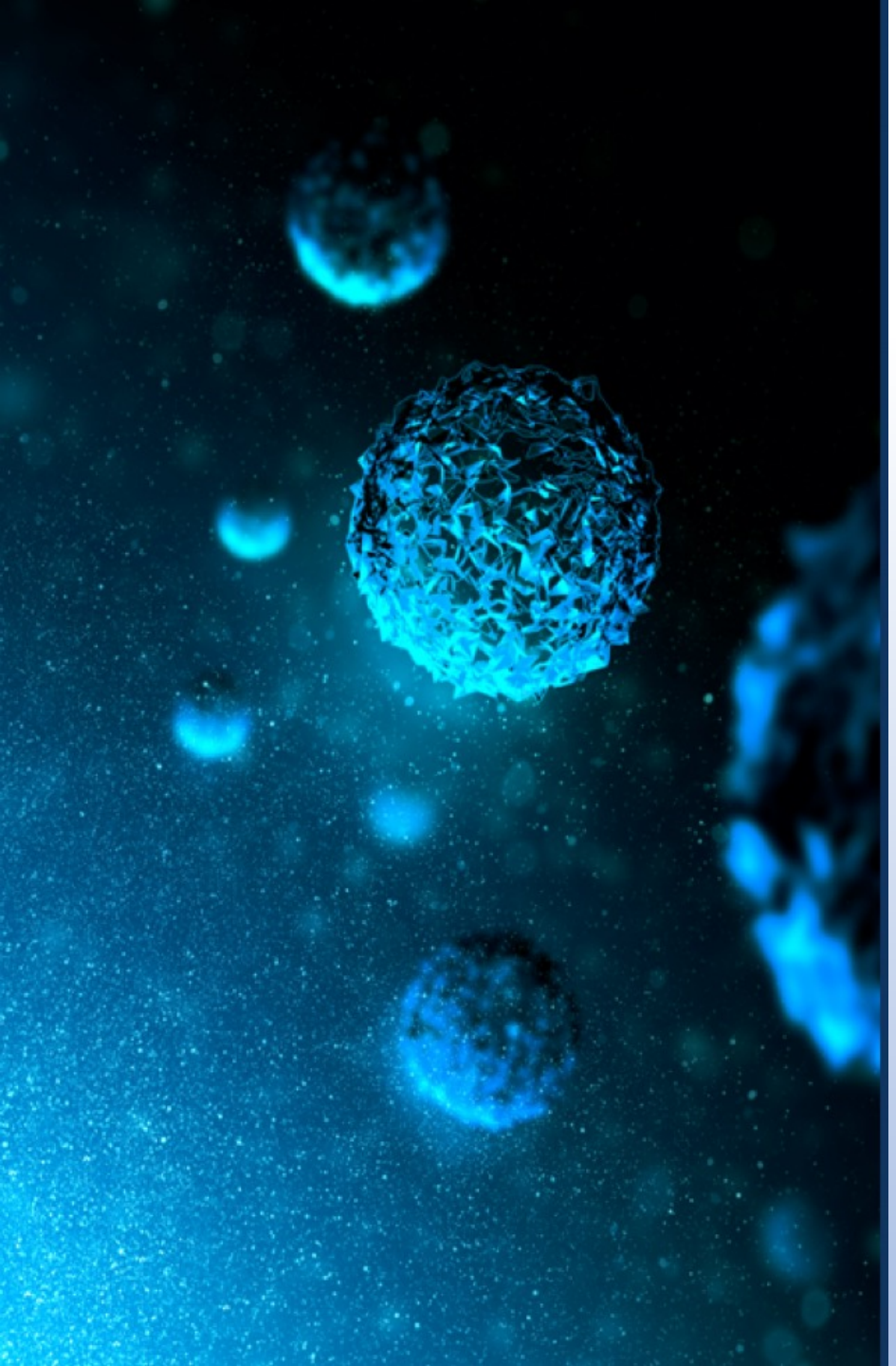
Correlation of Airborne Bioburden and Surgical Site Infection

The Operating Room: The major exogenous source of SSI is transmission by air

- Rooms with over 50CFU/m^3 are 2.6 times more likely to have postoperative infection than rooms with 10-20CFU/m^3 [1]
- SSI rates are rising for infection sensitive, high volume surgeries



1.Charnley J, Eftekhar N. Postoperative infection in total prosthetic replacement arthroplasty of the hip-joint. With special reference to the bacterial content of the air of the operating room. Br J Surg. 1969 Sep;56(9):641-9.
2.Travaseri R. Aerogenic contamination control in operating theatres. Doctoral thesis 2018. Dept. Orthopedic Surgery. Maastricht University, The Netherlands.

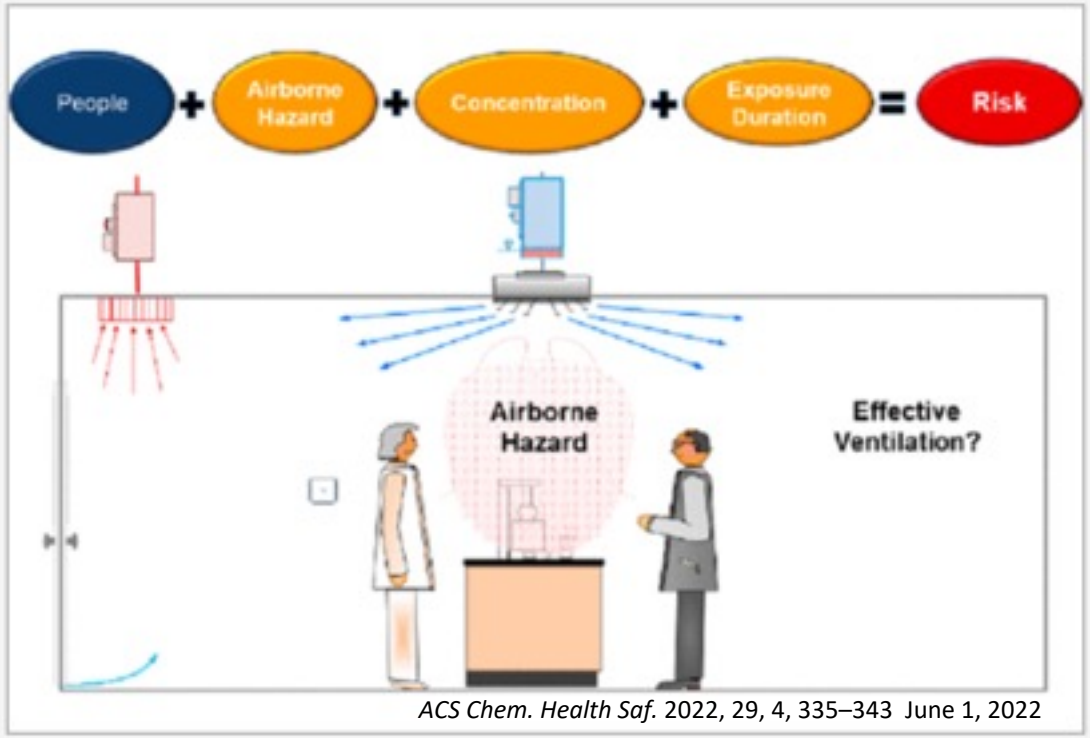


Ventilation:
The First Line of Defense

Role of ventilation in control of airborne transmission

Role of ventilation in airborne transmission of infectious agents in the built environment - a multidisciplinary systematic review 2007:

There is **strong and sufficient evidence** to demonstrate the association between ventilation, air movement, control of airflow direction and transmission/spread of infectious diseases to support use of negatively pressurized **isolation rooms**, in addition to the **use of other engineering control methods**.



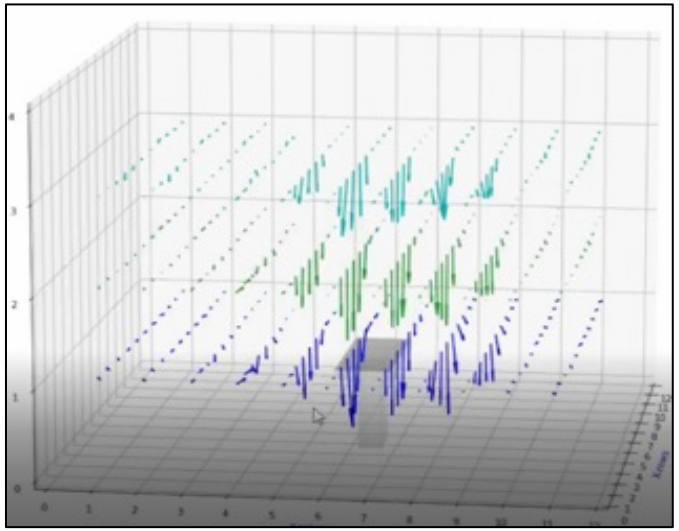
ACS Chem. Health Saf. 2022, 29, 4, 335–343 June 1, 2022

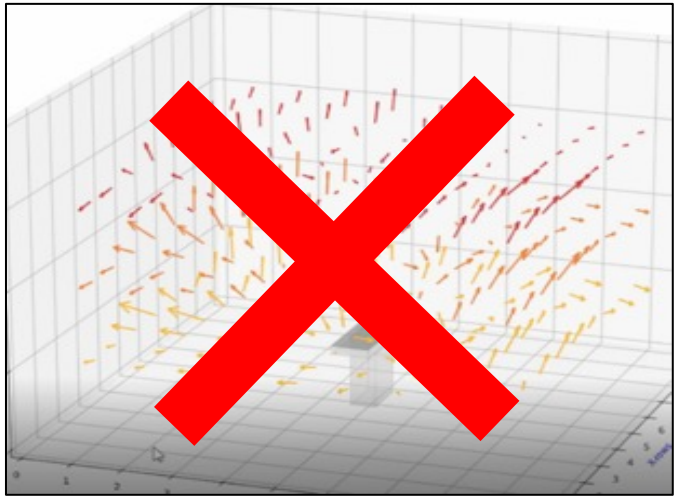
However, the lack of sufficient data on the specification and quantification of the **minimum ventilation requirements** in hospitals, suggest existence of a knowledge gap.

Li Y, et al. Role of ventilation in airborne transmission of infectious agents in the built environment - a multidisciplinary systematic review. Indoor Air. 2007 Feb;17(1):2-18.

Characteristics that minimize the presence of airborne bioburden in a space

- Positive pressure: Avoids flow of air from contaminated areas into adjacent areas (AIIR, OR)
- Direction: Consistent, perpendicular, downward flow (unidirectional) sweeps air down to exhaust vents
- Velocity: Air must be driven at speed that ensures
    1) uni-directionality
    2) high enough to overcome, obstacles and heat convection from staff
    3) minimize turbulence
- Temperature & Humidity: Can also influence transmission





Even when operating within parameters, no indication of performance, actual airborne bioburden (CFUs).

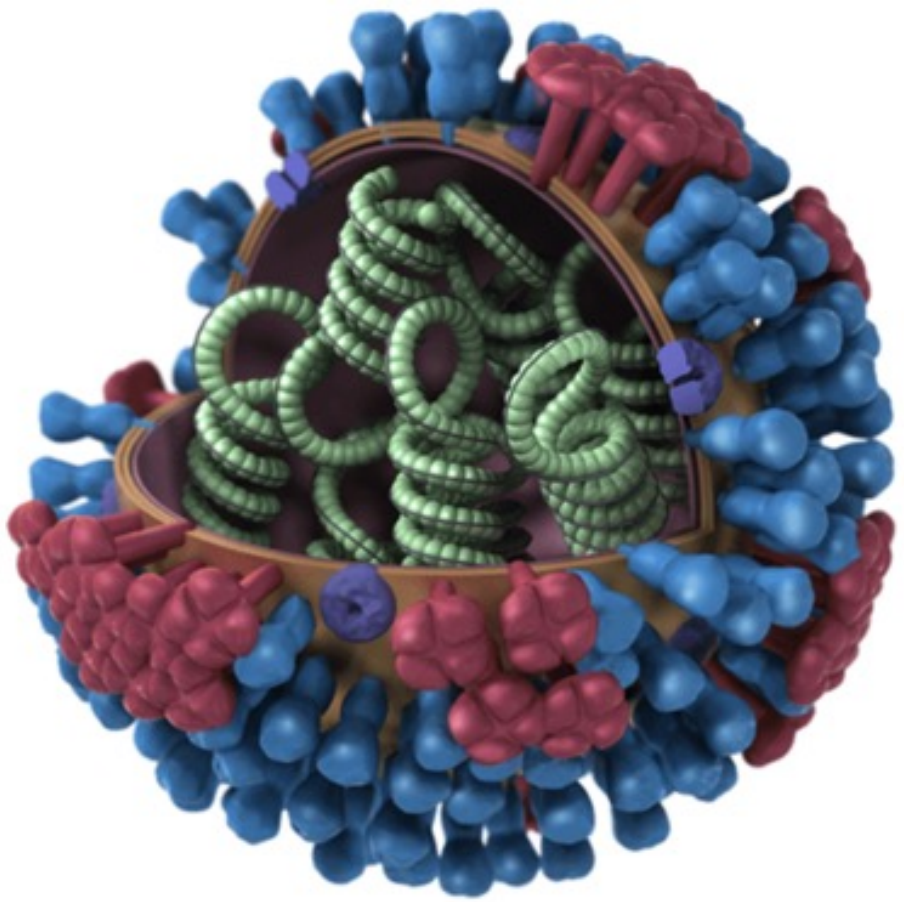
Standards/guidelines for management of airborne contamination
Minimum requirements - date to the 1960s

FGI & ASHRAE 170	CDC
• Air pressure relationships (positive/negative pressure based on risk and patient population (AIIR, OR) • Air Exchange Rate (ACH) • Filtration • Temperature • Humidity	• Relationship to adjacent area (positive/negative pressure – AIIR/OR) • Minimum ACH based on area (6-20 ACH) • Exhausted or recirculated • Relative humidity

US standards are **silent** on what constitutes a ”safe” level of airborne contamination.
Prescribe the **controls,** without identifying the **goal.**

Is more frequent ACH the answer?

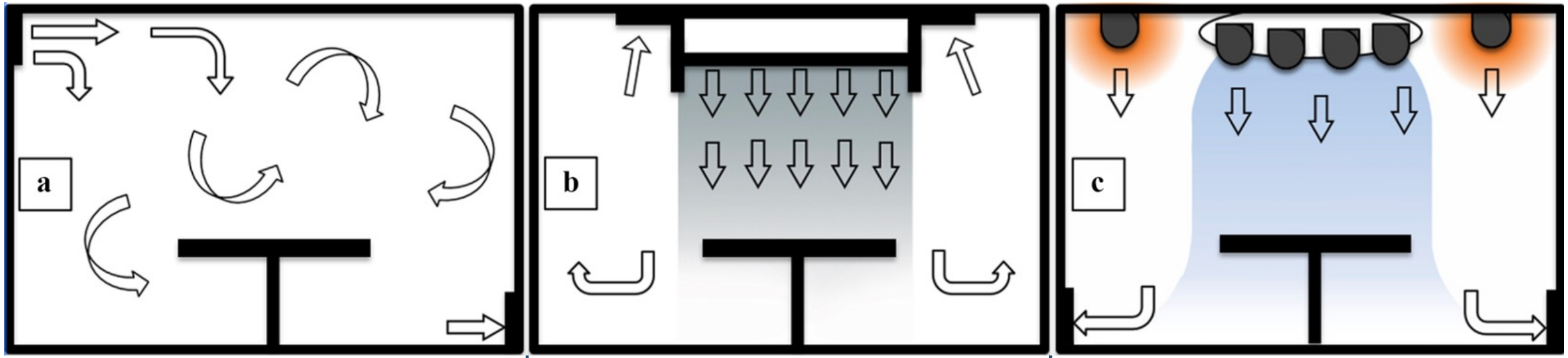
*"While the concentration of airborne infectious particles falls with increased air changes per hour, even very frequent air changing…….**does not radically reduce the airborne infectious particle count** ."*



Influenza A virus with subtypes. CDC

Galson E, Guisbond J. Hospital sepsis control and TB transmission. *ASHRAE Journal*. 1995;37(5):48–52

Three types of ventilation concepts



Turbulent mixed Airflow (TMA)

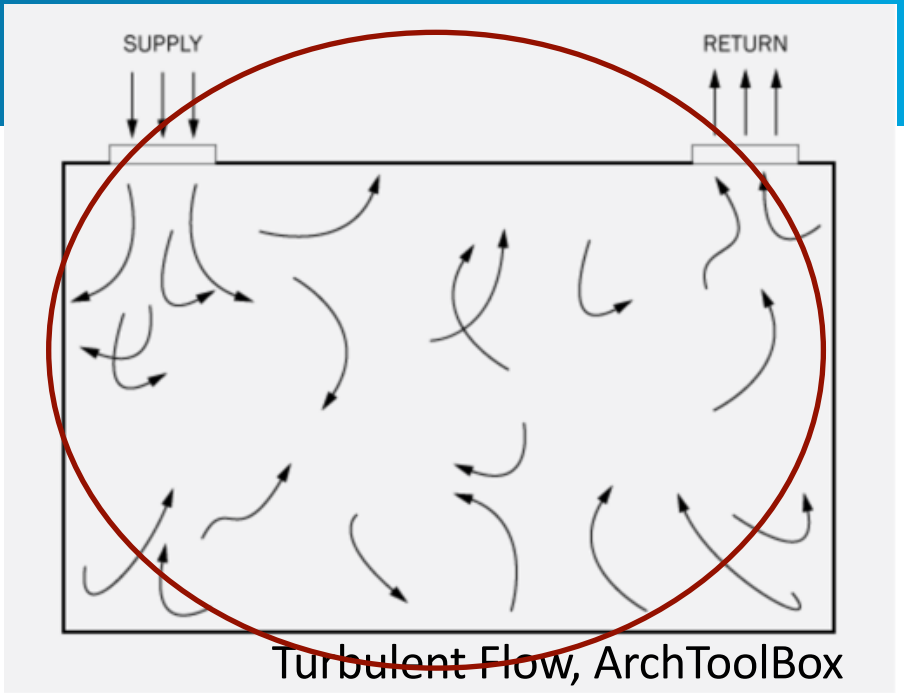
Uni-directional/Laminar Airflow (UDF/LAF)

Temperature-controlled AirFlow (TcAF)

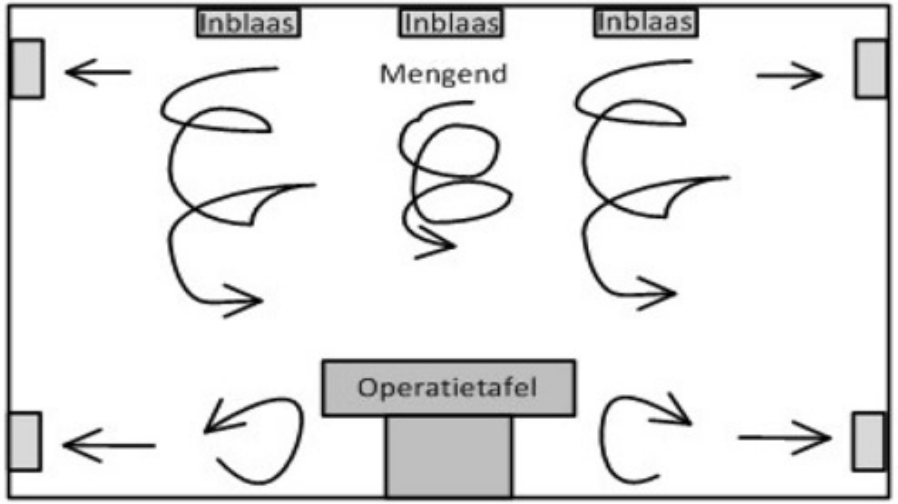
Differ in how airflow direction and velocity are managed.

Turbulent Mixed Airflow (TMA)

- Based on dilution principle: Filtered air streamed into space provoking *turbulent* mixing of clean air with contaminated air.
  - ➢ **Key parameter: Number of ACH**
- Air moves in an unpredictable manner, dictated by pressure and temperature differences. Air molecules constantly collide, contaminating air as particles are transported around the room before leaving via the return grille.[7]
- Inefficient - scales linearly, to halve CFU-level, requires 2X airflow.



Turbulent Flow, ArchToolBox



Where is TMA used?

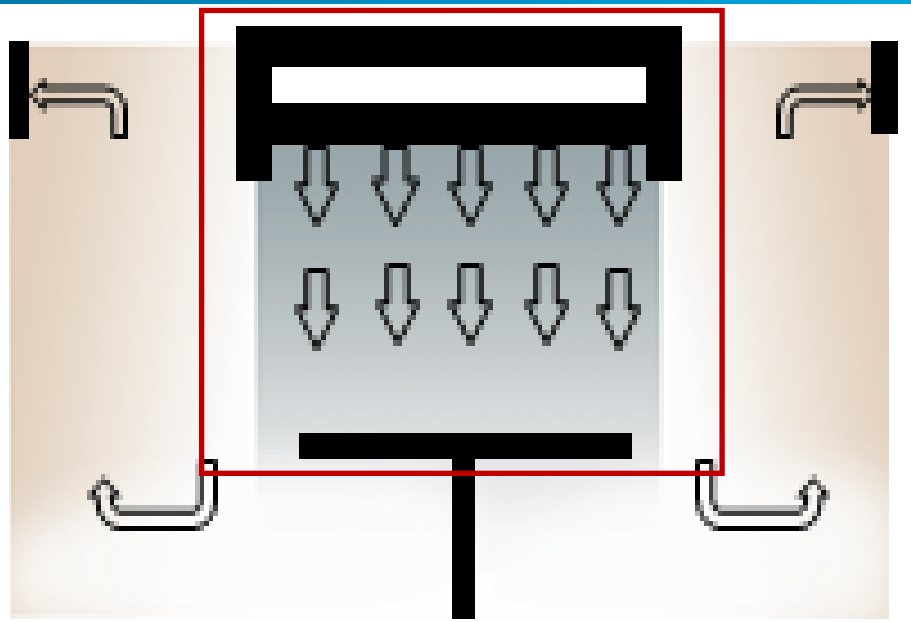
Everywhere except isolation, OR and specialized environments.

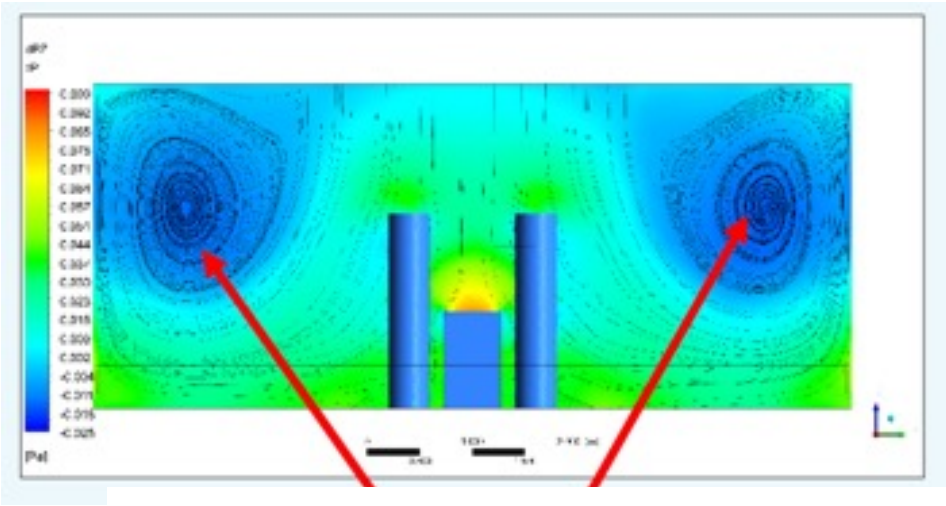
Laminar – Specialized environments (OR, pharmaceutical compounding)

- Air should flow in a straight, unidirectional path, steady velocity and parallel streamlines
- Creates a limited *clean zone* (<10CFU/m^3)
- Easily *disrupted by objects in pathway,*

  challenged by *vortices in the periphery*
- Mean values of airborne CFUs outside

  protected zone: *55-fold higher* than values inside [1]
- Based on growing body of evidence, no longer recommended by CDC or WHO for joint arthroplasty [2,3]





CFD Simulation –Royal Inst. Tech, Sweden

1-Benen T, Wille F, Clausdorff L. Influence of different ventilations systems upon the contamination of medical devices. *Hyg Med*. 2013; 38–41
2-Berríos-Torres SI, Umscheid CA, Bratzler DW, et al. Centers for Disease Control and Prevention Guideline for the Prevention of Surgical Site Infection, 2017. *JAMA Surg.* 2017;152(8):784–791
3 -Global guidelines on the prevention of surgical site infection. World Health Organization. 2016. http://www.who.int Accessed July 9, 2020.

CFU heat map: Live case w/ conventional ventilation

Measurements taken in 3 locations:

- Wound/surgical field
- Instrument tables
- Periphery (case carts/back tables)

The basis of design is not always operational reality.

LAF no longer recommended

Based on a growing body of evidence LAF is no longer recommended for infection sensitive surgery: [16-20]

- CDC: 2003, recommended LAF for joint surgery. 2017, back-tracked, LAF is an *"unresolved issue."* [21]
- WHO: 2017 conditional recommendation *"LAF should not be used to reduce the risk of SSI for patients undergoing total arthroplasty."* [22]
- PJI Global Consensus Group

  "LAF may no longer be recommended." [23]

"There are several explanations for the wide variability of reported results with LAF.

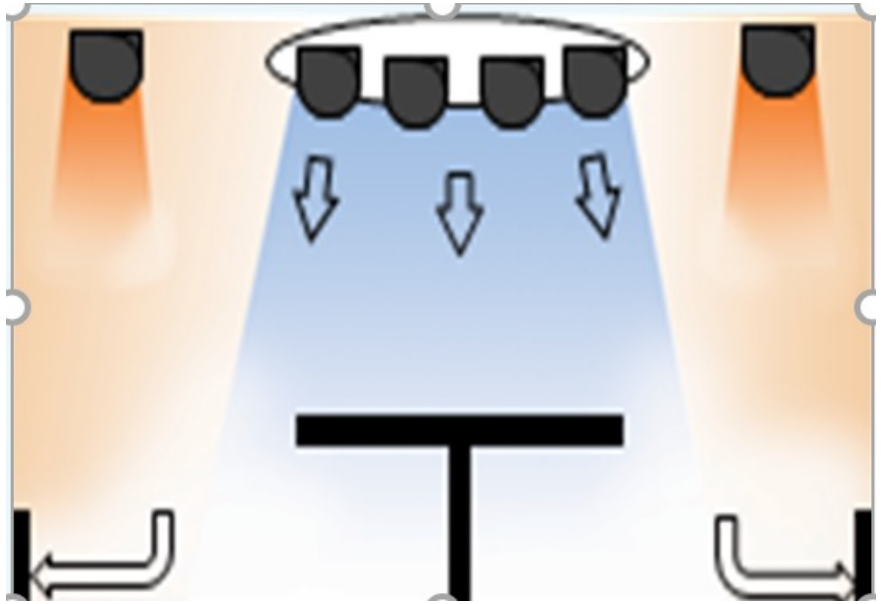
*First**, the parallel airflow of the LAF system can be easily disrupted by objects or personnel**.*

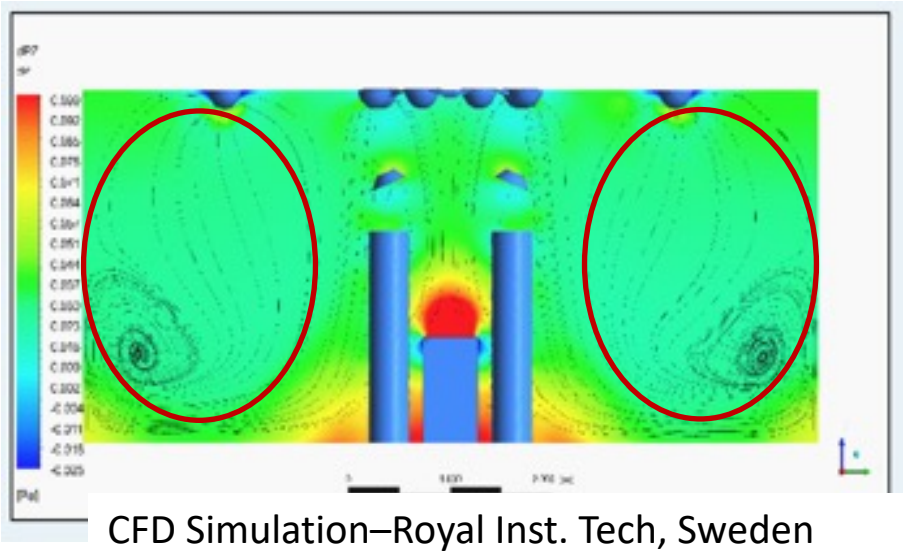
Second, the association between air contamination and the deep infection rate is logarithmic. ***A 10-fold reduction in air contamination is necessary to halve the infection rate.***

Third, ***LAF systems fail to address the environment outside of the immediate LAF zone****, leaving scant room for implants, instrument trays and tables. Laminar airflow systems may be associated with the contamination of these areas by blowing bacteria off personnel and the floor onto instrumentation and other personnel."* [24]

Temperature-controlled Air Flow (TcAF): Operating room, pharmacy, radiology, central sterile supply

- HEPA filtered air dispersed from air showers at 1.5°C cooler than ambient room temperature
- Temperature differential creates gravity-driven down-flow, consistent throughout the space
- Fall speed of the air (>0.25 m/s), counteracts heat convention from staff, lamps & obstacles
- Air supplied in the periphery prevents stagnation zones
- Maintains *entire room* at <10CFU/m^3
- Temperature /humidity: Set at any level to ensure patient safety, staff comfort



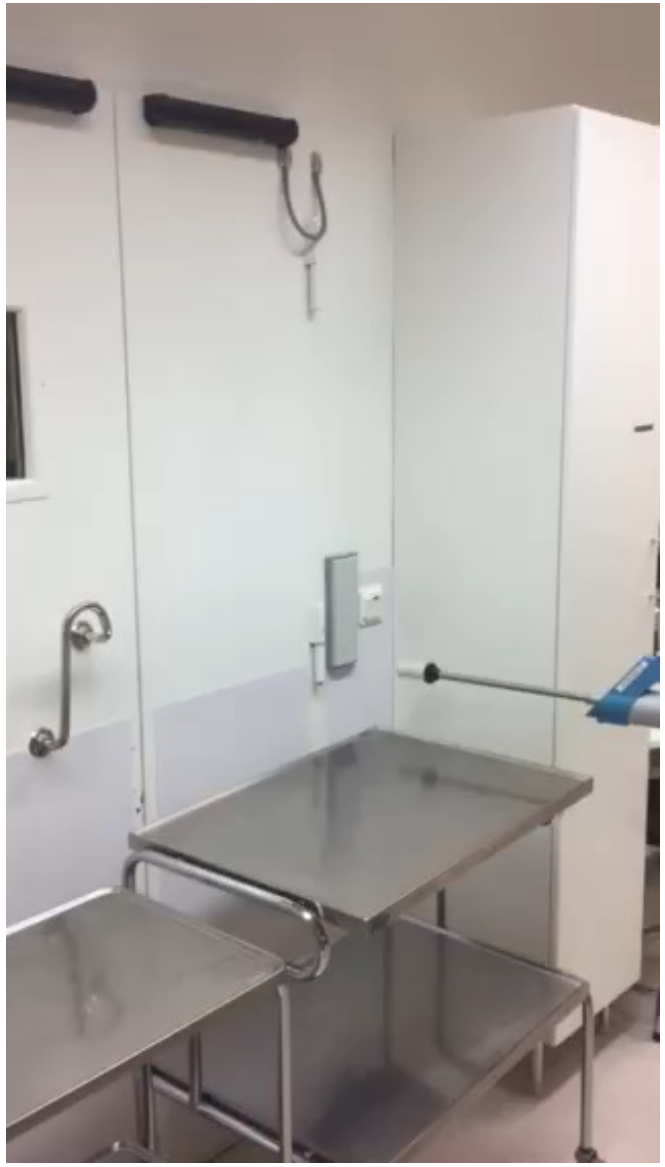


CFD Simulation–Royal Inst. Tech, Sweden

Alsved M, et al. Temperature-controlled airflow ventilation in operating rooms compared with laminar airflow and turbulent mixed airflow. J Hosp Infect. 2018 Feb;98(2):181-190

Turbulent Mixed Airflow (TMA)

Laminar Airflow (LAF)



Temperature-controlled Airflow (TcAF)

Standards development in the European Union: Movement to *performance based standards*, limitations on CFUs by risk/service

EU countries are moving away from prescriptive engineering standards to performance-based standards:

Approach that prescribes the environmental outcome expected, not the means by which the result is to be achieved.

- Measurement ⟶ Management
- Safer environments for patients and personnel

Fig. 1. Parvizi J, Barnes S, Shohat N, Edmiston CE Jr. Environment of care: Is it time to reassess microbial contamination of the operating room air as a risk factor for surgical site infection in total joint arthroplasty? Am J Infect Control. 2017 Nov 1;45(11):1267-1272

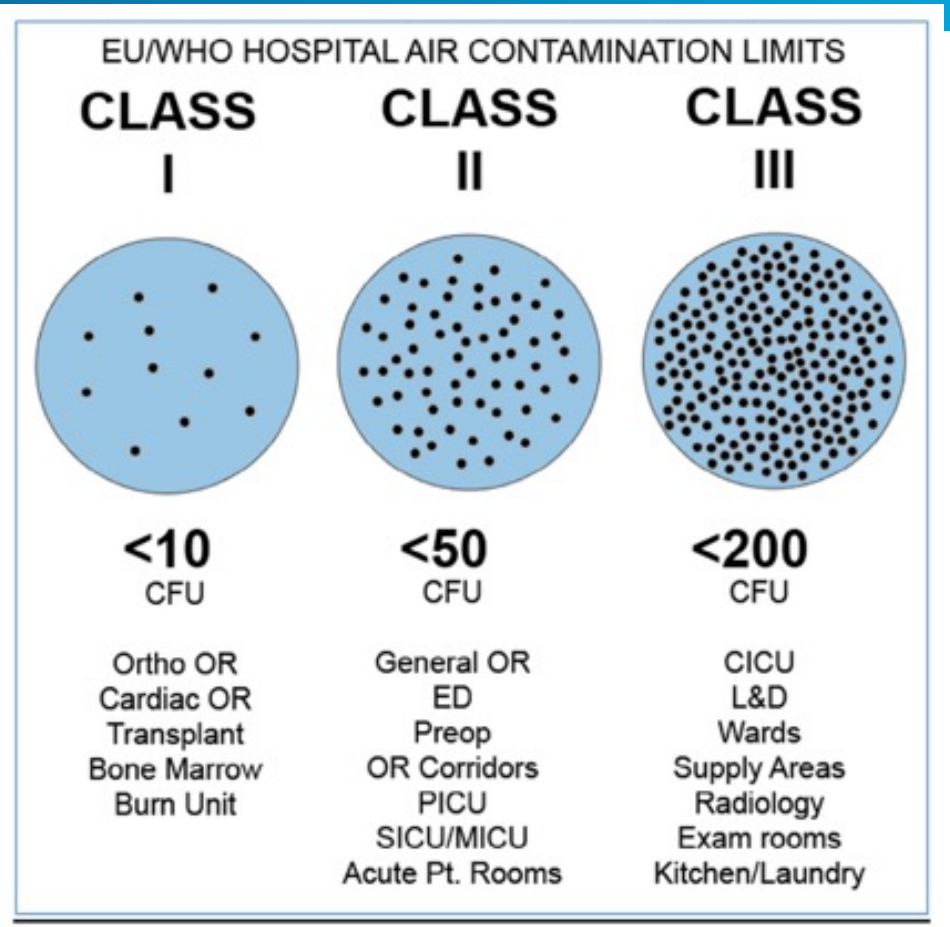
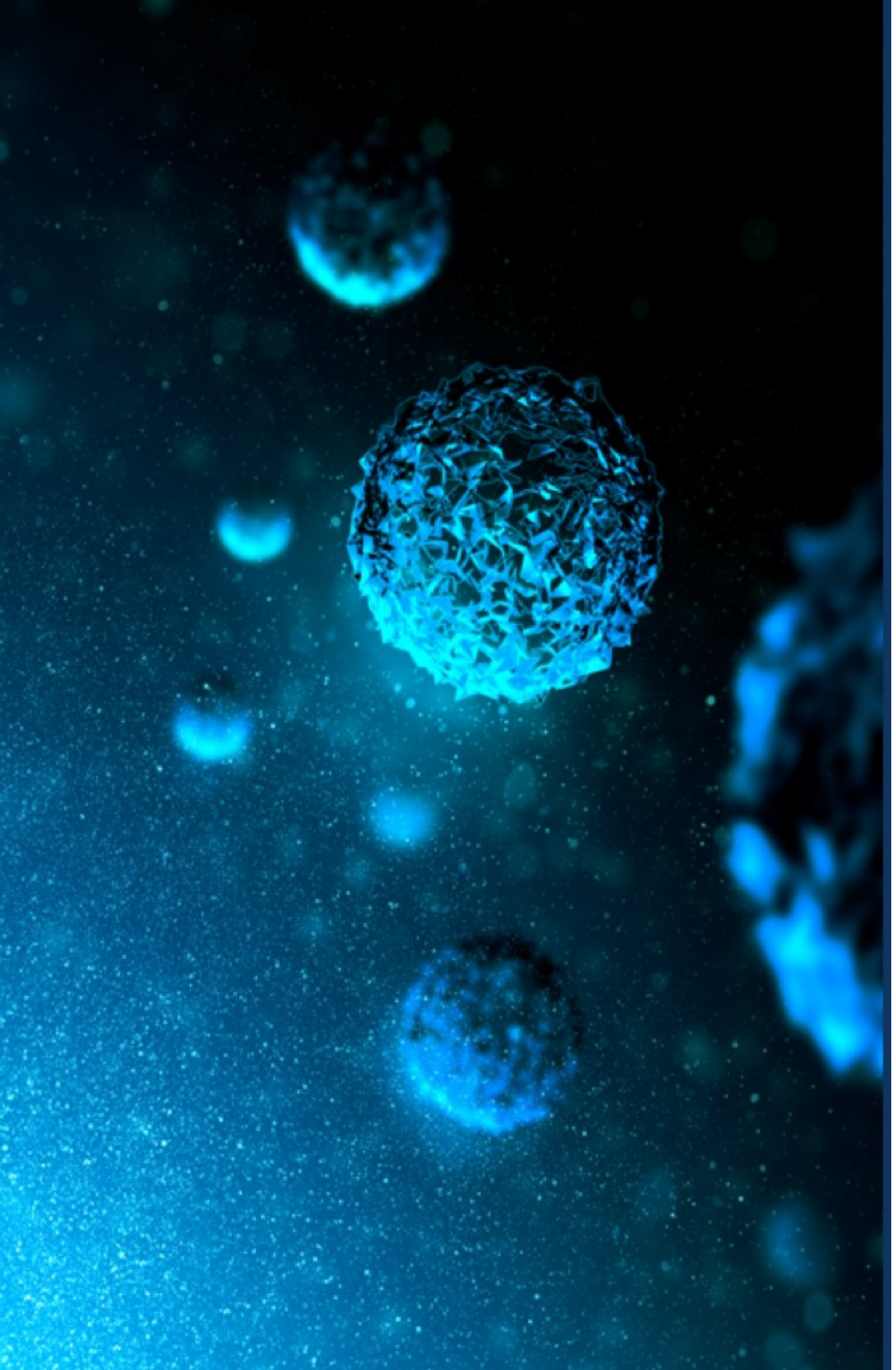


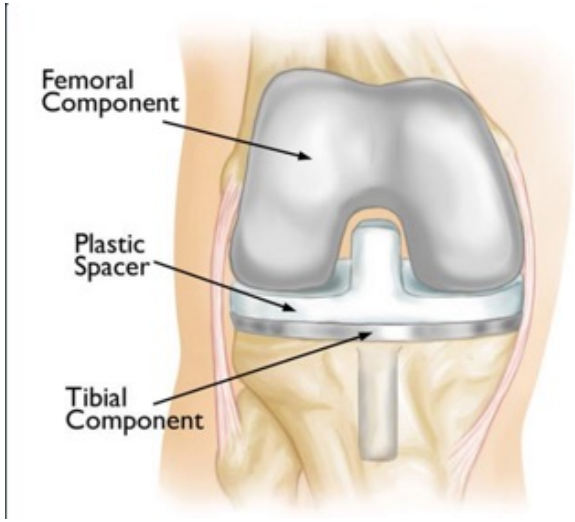
Fig 1. Propose EU-WHO standards for contamination of hospital room air: class I, <10 CFU; class II, <50 CFU; and class III, <200 CFU. Hospital OR fall within class I standards. 39 CFU, colony forming units; ED, emergency department; EU, European Union; Preop, preoperative; Pt., patient; OR, operating room pediatric intensive care unit (PICU); surgical intensive care unit (SICU); medical intensive care unit (MICU); cardiac intensive care unit (CICU) and labor and delivery (L&D). WHO, World Health Organization.



Comparative Analysis: Performance of Ventilation Concepts Against Airborne Microbial Contamination

Risk factors with an airborne component

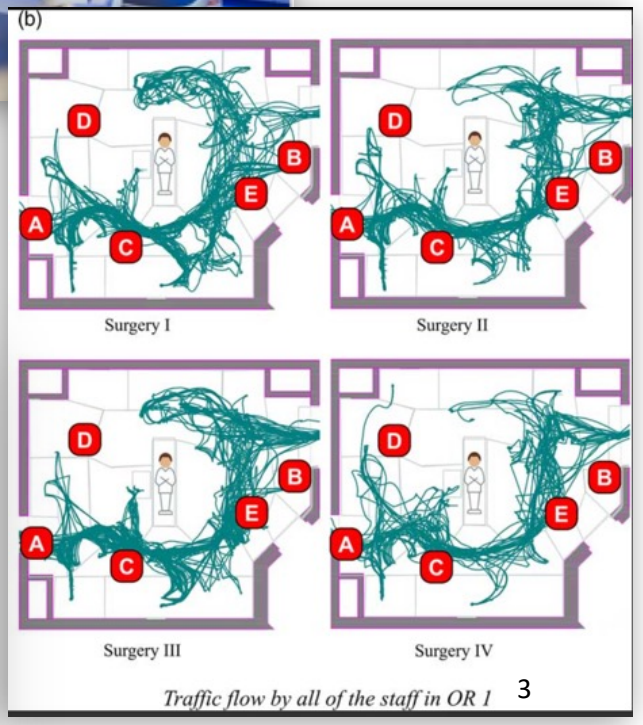
- **Number of personnel in the OR**
  - Humans disperse over 10M skin squames per day
  - Over 1M contain bacteria
- **Movement of personnel and equipment**
- **Length of procedure**
- **Type of procedure**
- **Presence of an implant**
- **Door openings/closings**
- **Exposure of air, surfaces, equipment, sterile implants, instruments and devices to air contaminants**



Measurement at-rest vs. in-use

The majority of the bacteria in the OR comes from personnel (shedding skin squames), movement of people, equipment and doors, heat convention from people and equipment.

- We shed about 1M skin squames per day, ~20% carry bacteria.
- The microbial level in OR air is directly proportional to the number of people moving about in the room.[1]
- In one study, traffic flow, number of people and duration of surgery explained 68% of the variance in total CFU/m^3.[2]



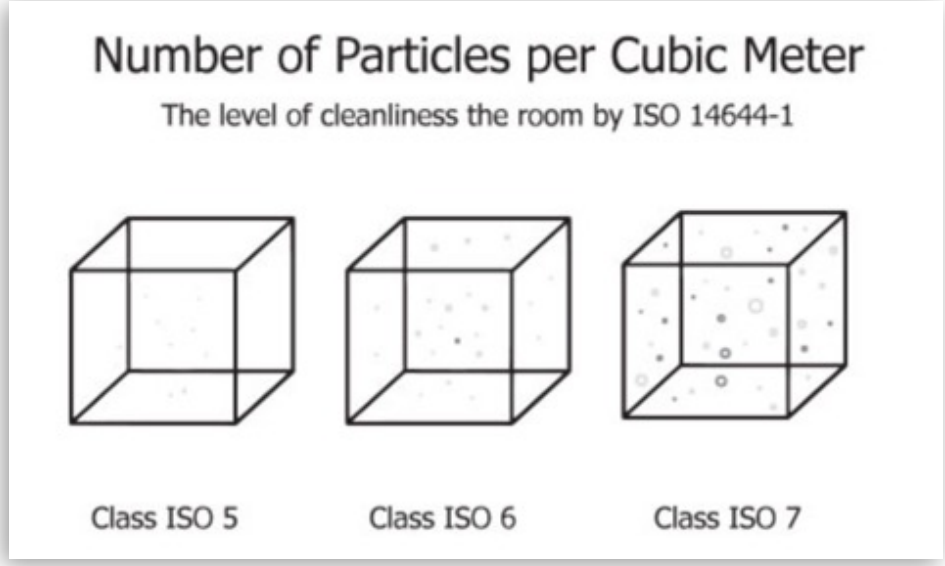
Measuring a room at rest is not a substitute for measuring a room in-use as the primary conditions that contribute to airborne microbial contamination are not present.

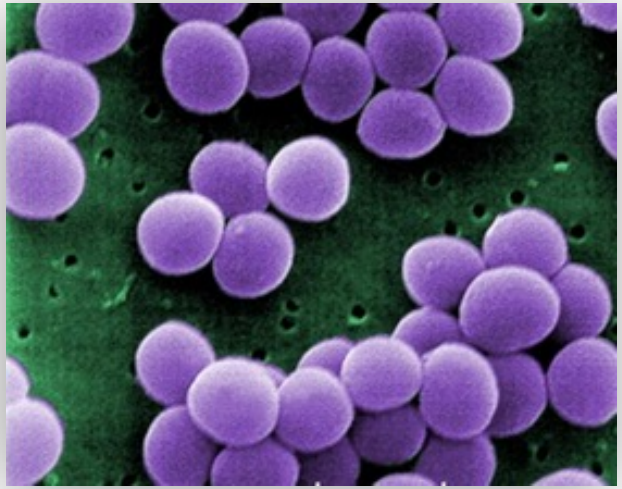
1. Fu Shaw L, et al. Factors influencing microbial colonies in the air of operating rooms. BMC Infect Dis. 2018 Jan 2;18(1):4.
2. Andersson AE, et al. Traffic flow in the operating room: An explorative and descriptive study on air quality during orthopedic trauma implant surgery. Am J Infect Control. 2012 Oct;40(8):750-5.
3. Taaffe, K., et al. (2018). The Influence of Traffic, Area Location, and Other Factors on Operating Room Microbial Load. *Infect Cont Hosp Epi 39*(4), 391-397.

Particle measurement is not a substitute for bacterial measurement

Systematic review of particle counting as a potential substitute for CFU measurement, 11 studies. 2 reported strong correlation between particles and CFU (Rp = 0.76 and Rc = 0.74). Remaining studies observed moderate correlation (n = 3), low correlation (n = 3), or no correlation (n = 3).[1]

Once a baseline has been obtained, particle counting can provide an *indication of changes* in the overall level of airborne microbial contamination, but particle counting is not a viable substitute for measurement of actual airborne microbial contamination.





1. Stålfelt F, Svensson Malchau K, Björn C, Mohaddes M, Erichsen Andersson A. Can particle counting replace conventional surveillance for airborne bacterial contamination assessments? A systematic review using narrative synthesis. Am J Infect Control. 2023 May 12:S0196-6553(23)00360-7

Comparative analysis of ventilation concepts

Healthcare design/build engineering firm.

Objective

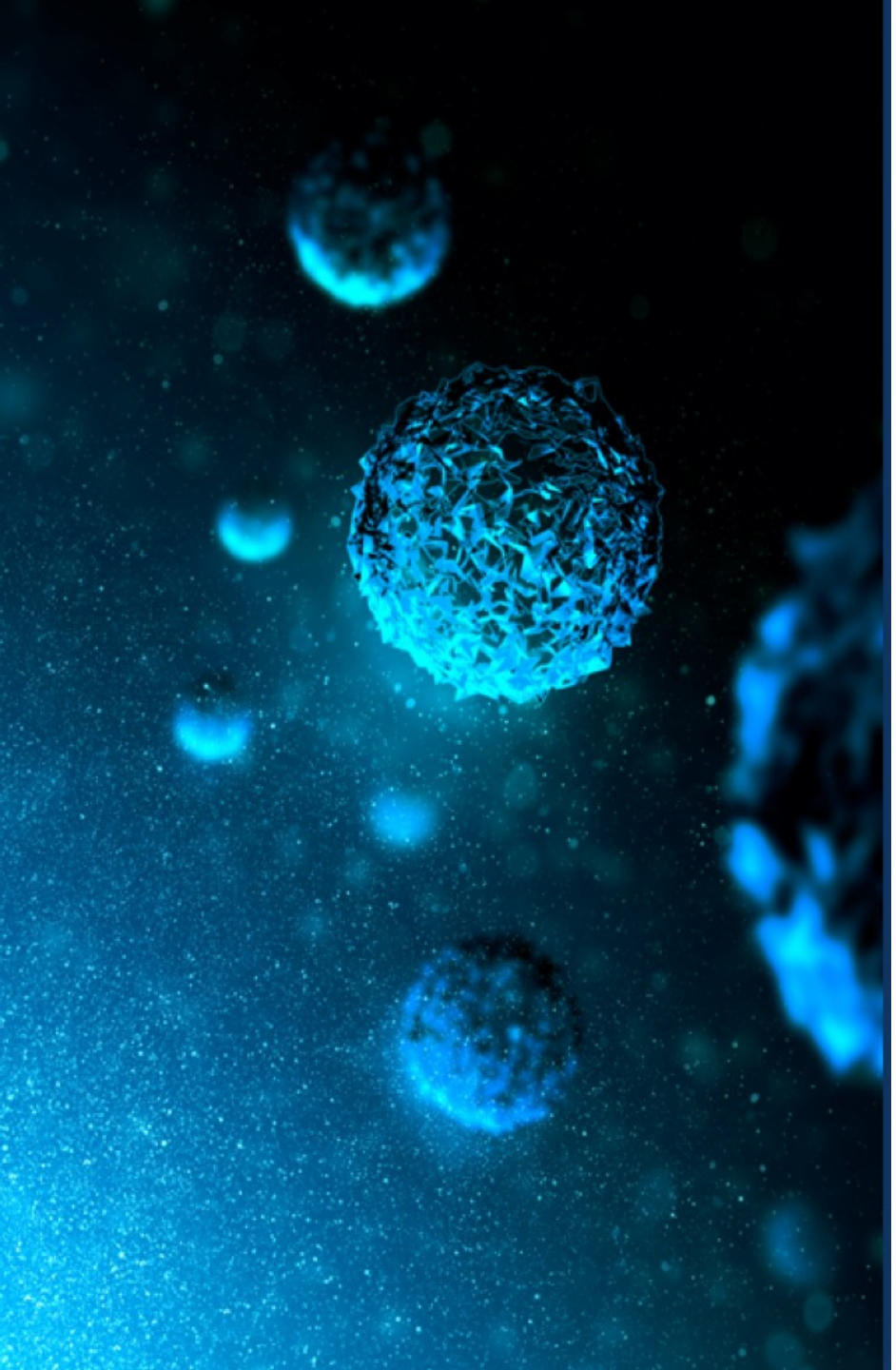
To compare the three primary ventilation concepts to determine relative *performance* against airborne microbial contamination as measured in particle counts and CFUs.

Conditions

- All ORs approximately 50 m2 and with a height of 3 meters.
- For all measurements temperature and humidity were approximately 21 ˚C / 55 %.
- HEPA filtration minimum quality of H13, all filters tested before study commenced.
- All air volumes dedicated to the ventilation system, air volume set for optimal performance.
- All measurement tools were calibrated.

Methods

- Both particle measurements and bacterial measurements were undertaken.
- All systems studied “at-rest” to determine general cleanliness of the room, ensure filtration system working properly
- LAF and TcAF systems were studied “in-use” to determine efficacy in controlling airborne microbial contamination during routine surgical activity



Methods:
Comparative Analysis of Ventilation Concepts

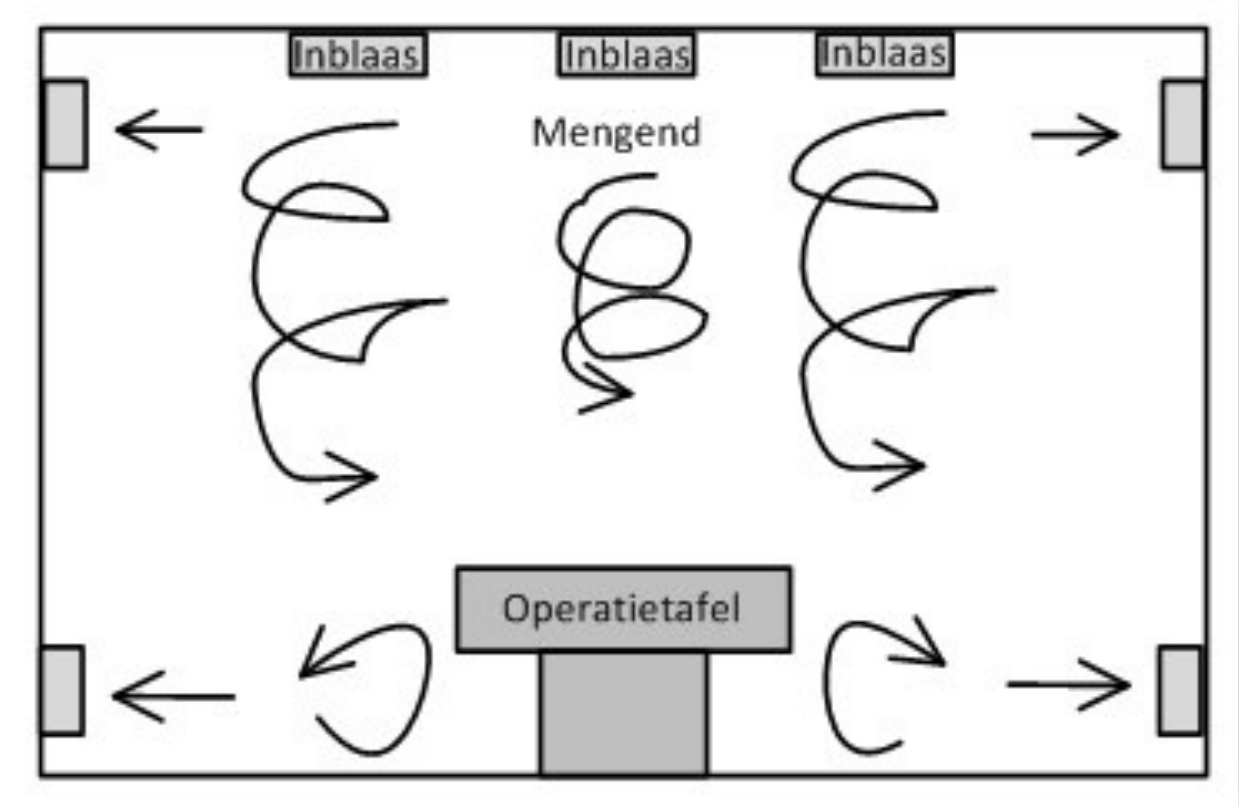
Methods

- Particle measurements taken in rooms “at-rest” to determine overall environmental cleanliness (filtration, surface disinfection) prior to study
- LAF and TcAF systems studied “in-use” to determine efficacy in controlling airborne microbial contamination during routine surgical activity
  Both particle measurements and bacterial measurements undertaken.

- Measurement of CFUs “in-use:”
  - During surgery with active air sampler,
  - Knife time ≥45 minutes
  - Samples taken at two locations
    1) At maximum distance of 2 feet from (patient) wound area (with sterile tube/hose),
    2) Close to the sterile instrument table and
  - Three samples taken at each location

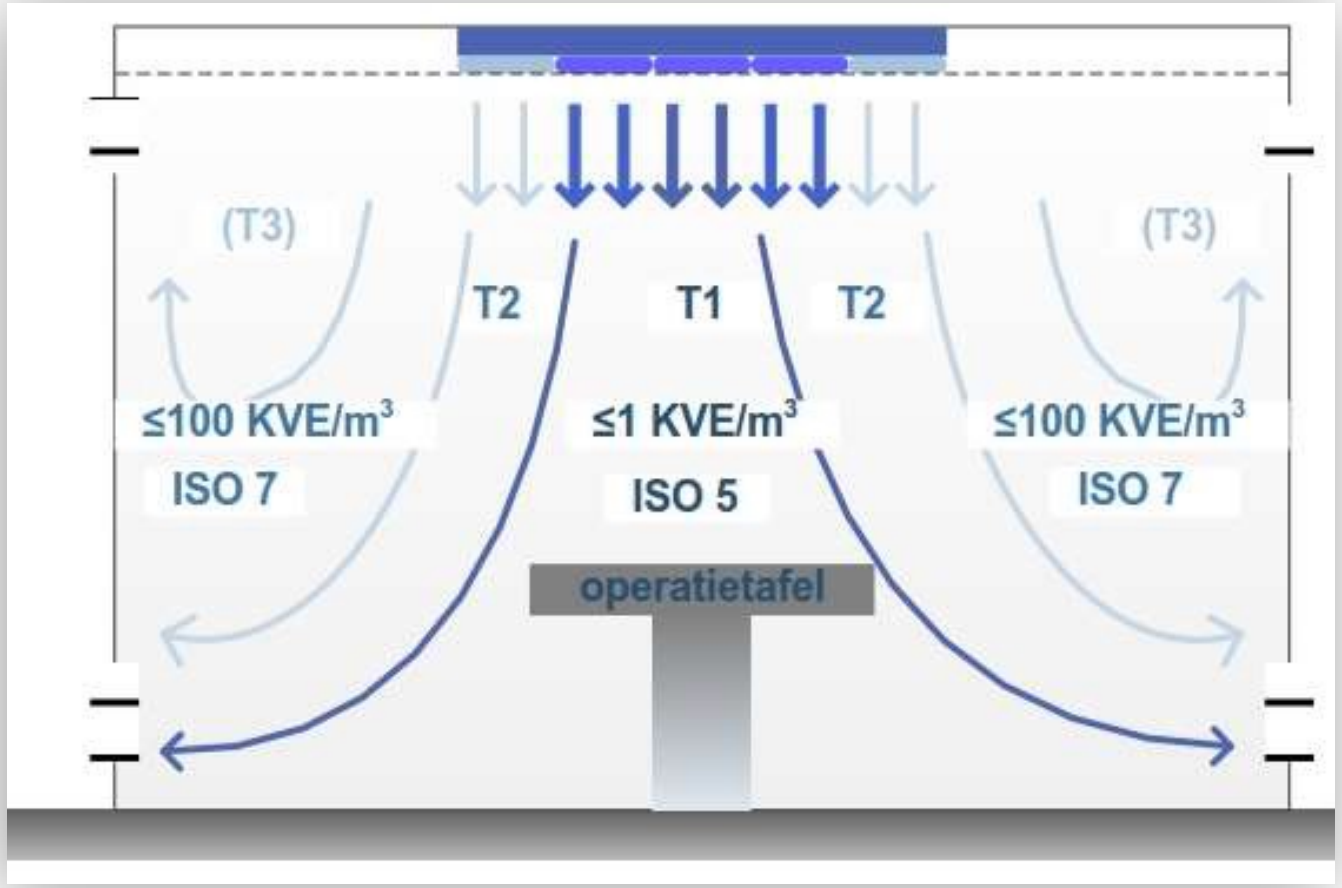
Configuration: Turbulent-Mixed Air Flow system

- Air volume of 5000 m3/h
- Air inserted into the space with a speed > 0.5 m/s



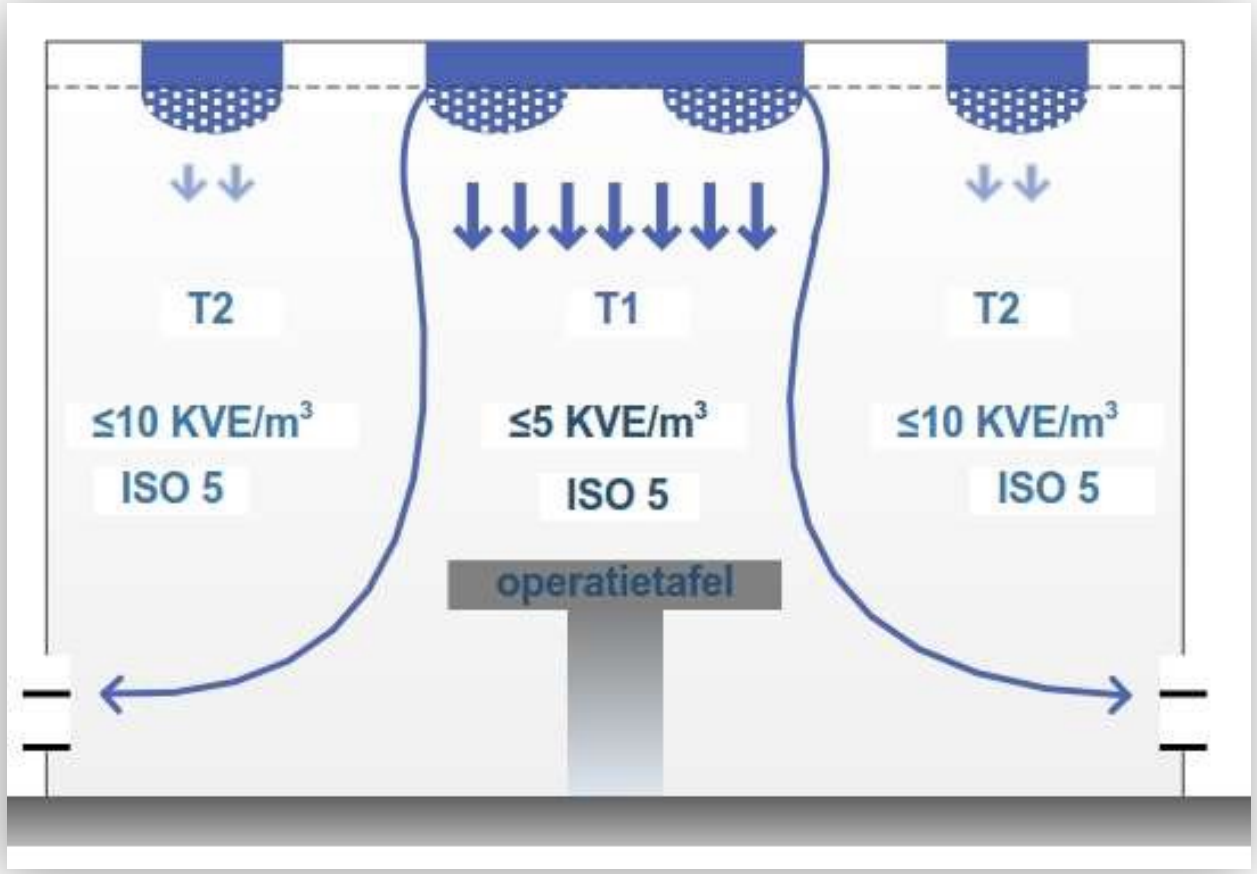
Configuration: Laminar Air Flow system

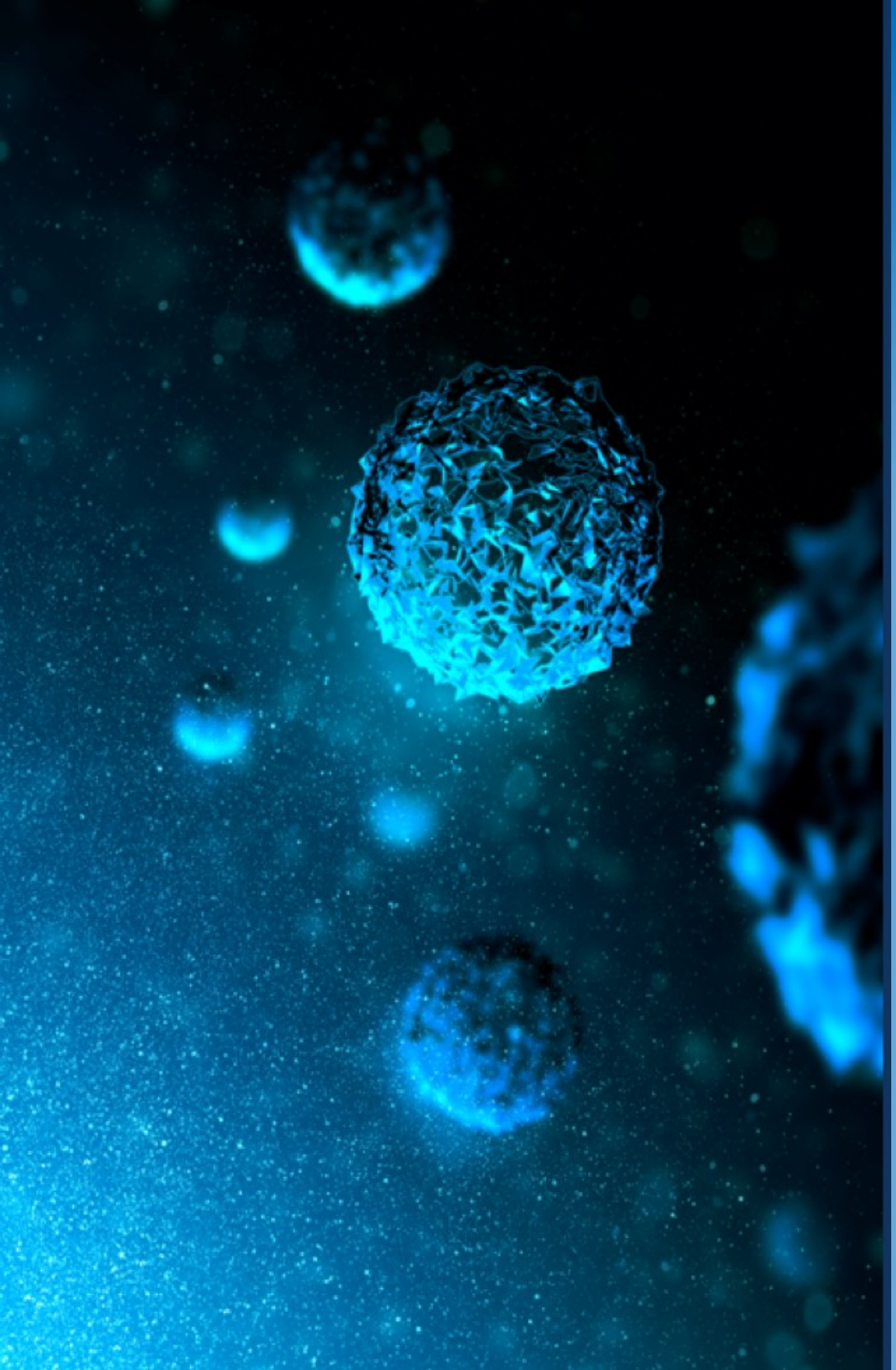
- Plenum in the center of the room
- Size of plenum: 3200 x 3200 mm
- Air volume: 11.000 m3/h
- No air supply in periphery



Configuration: Temperature-controlled Air Flow system

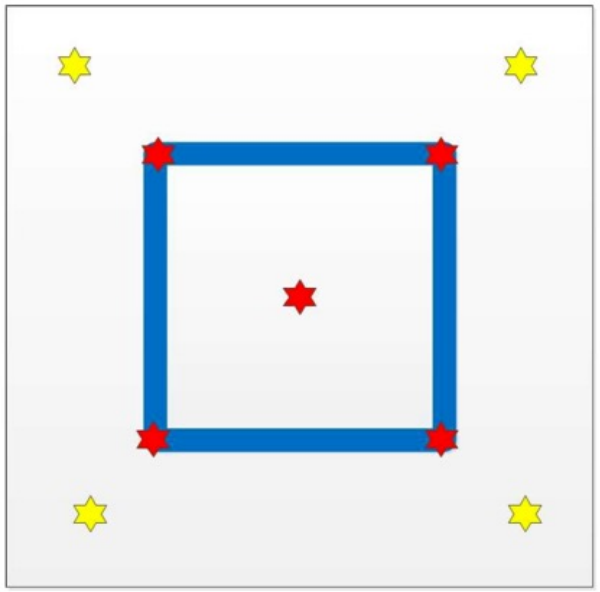
- Central plenum with 8 air showers
- Around the plenum, 12 air-showers positioned in periphery
- Total amount of air: 6.800 m3/h
- Air speed: > 0,25 m/s at the table
- Temperature difference between the central plenum and remainder of room: 2°K



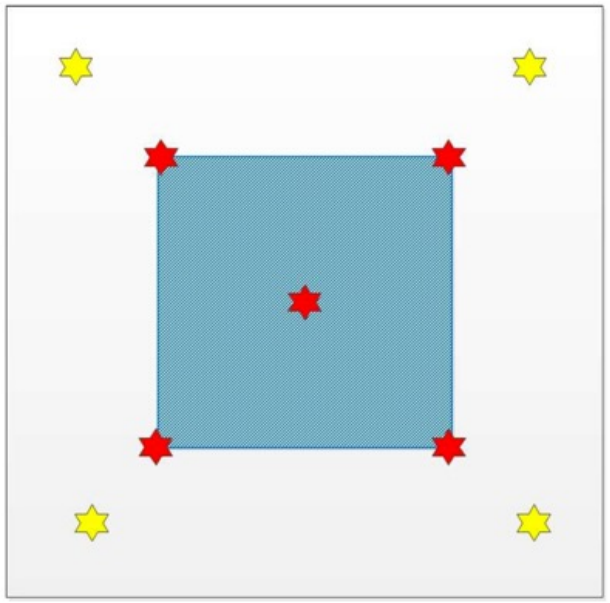


Results:
Comparative Analysis of Ventilation Concepts

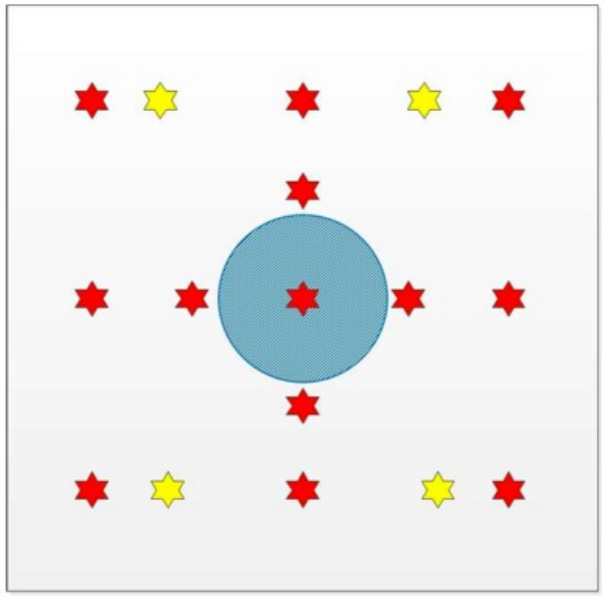
Particle measurement, by system, sampling diagram



Turbulent Mixed Air Flow



Laminar Air Flow



Temperature-controlled Air Flow

Contamination release

Measurement points

Particle measurements, by system, “at-rest"

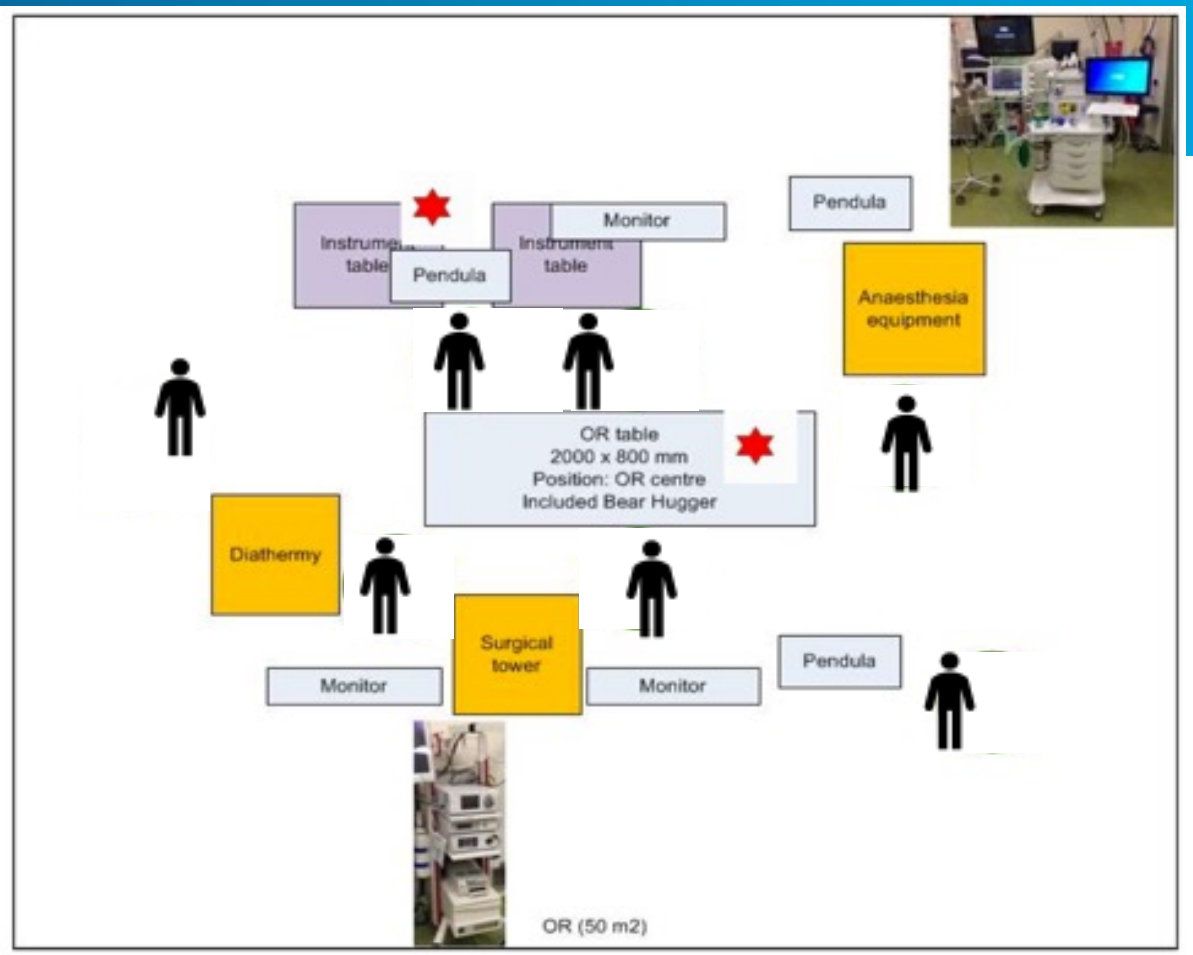
Unoccupied Rooms At-Rest
Particle Measurements

Ventilation system	Result particles	
	Centre	Periphery
TMA system	381,503	318,503
LAF system	0	117,748
TCAF system	0	163

Even at rest, TMA and LAF rooms have significantly higher levels of particles.

CFU measurements, “in-use"

- Duration of procedure, minimum of 45 minutes
- 7 OR personnel, movement as procedure dictates
- All equipment in use as procedure dictates
- Samples taken: 1)at the wound, 2) at the instrument table.



RESULTS

Ventilation system	Result cfu/m^3	
	Wound area	Instrument table
LAF system	0	4
TCAF system	0	< 1

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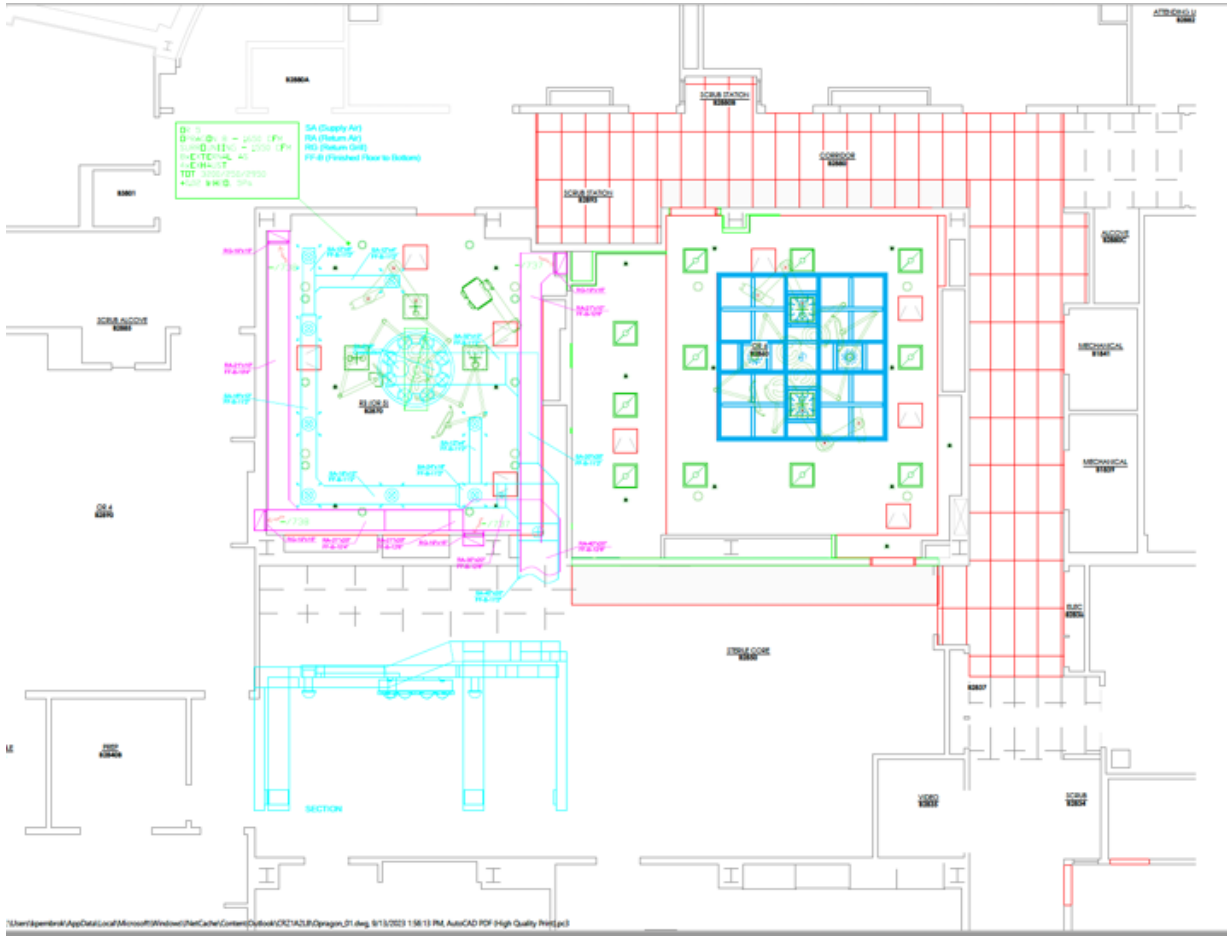
TcAF installation at URMC

TcAF air distribution



Particle testing of new operating rooms

Rooms were “broom cleaned”only prior to testing.

Significantly lower counts in OR 5 with TcAF system.

A testament to the physics of the design.

AVG PARTICLES @ 0.5µ and larger (PPCM)								
NUMBER	OR-1	OR-2	OR-3	OR-4	OR-5	OR-6	OR-7	OR-8
1	2,189	8,934	1,447	953	36	2,754	7,239	14,125
2	1,165	9,994	1,589	4,977	103	6,286	6,815	12,889
3	1,059	10,947	4,873	6,601	138	5,932	7,592	11,300
4	1,483	4,202	3,354	6,778	703	4,273	7,204	9,640
5	918	4,873	1,518	1,553	197	2,860	4,379	7,062
6	388	1,165	776	177	274	1,094	35	1,377
7	211	3,520	35	0	38	1,024	0	35
8	494	9,570	5,791	2,506	62	2,154	2,472	6,886
9	105	2,295	1,765	4,413	117	2,966	3,637	7,486
10	0	1,342	317	71	39	317	423	70
11	35	600	35	35	191	317	812	565
12	1,059	4,343	1,907	1,942	37	1,342	1,306	8,016
13	1,488	635	847	35	39	529	1,695	8,722
14	388	565	4,237	2,400	88	211	1,200	3,919
15	247	529	494	3,318	68	776	3,496	4,061
16	706	1,271	988	1,447	79	1,483	2,789	4,449

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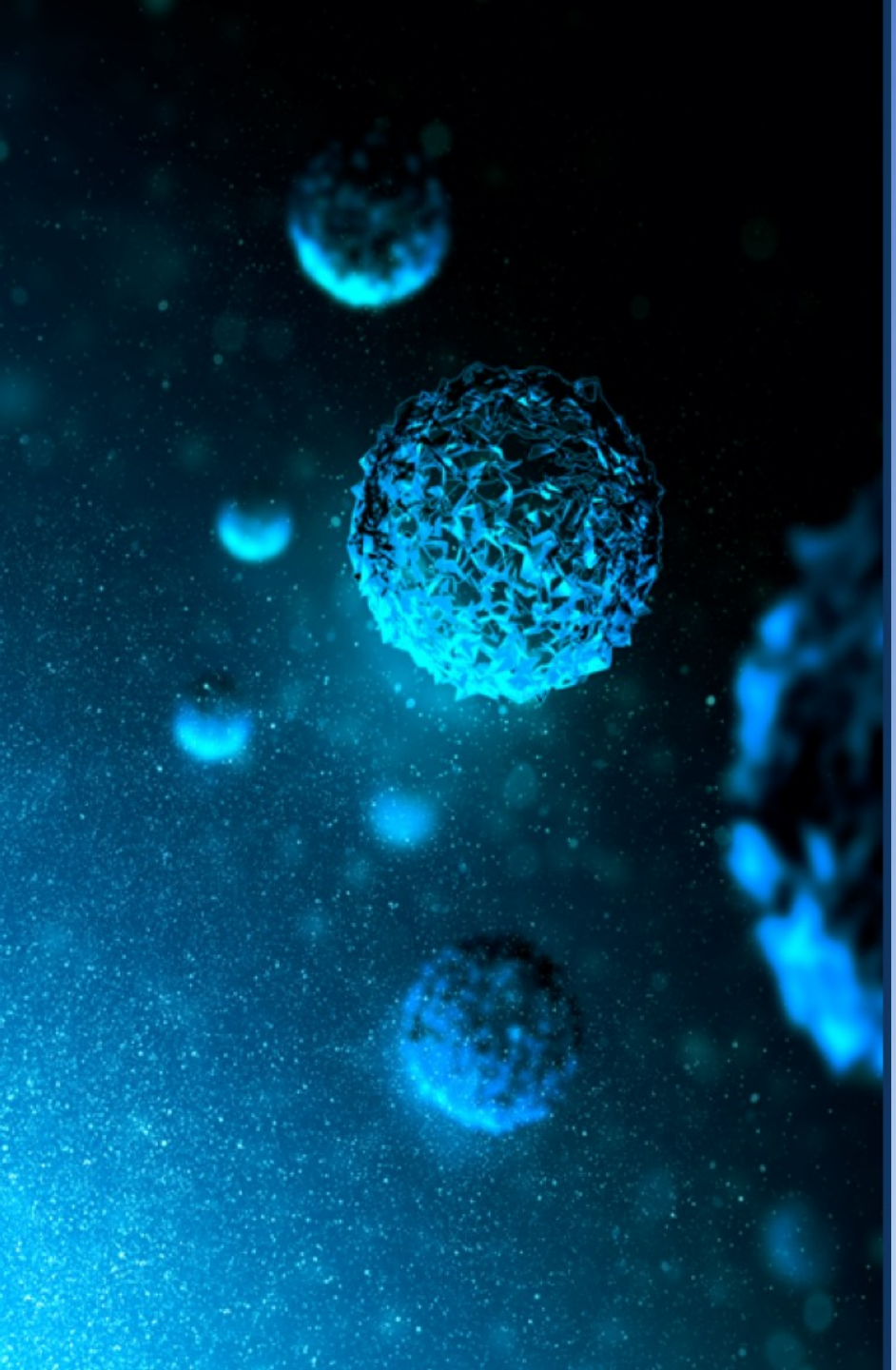
OR 5 with TcAF

US standards are not keeping pace
Countries with limitations on OR airborne contamination

Country	CFU Limits	ISO Clean Room	Document	Comments
Australia	Class 6, ISO 14644-1	ISO Class 6	ANZ/NZS ISO 14644-1	
Sweden	≤10 CFU/m^3 for procedures utilizing implants		Standards Institute Teknisk Specification SIS-TS 39	
Netherlands	≤10 CFU/m^3 for procedures utilizing implants			Mean value of ≤5 CFU/m3 targeted, to ensure ≤10 CFU/m3
Germany	Recommended <4 CFU/m^3, limit of <10 CFU/m^3		Standard DIN 1946-4-2008 Standard VD 2167	3 classes of rooms
Switzerland	<10, 50 & 200/CFU/m^3 depending on risk			3 classes of rooms by risk
France	≤20 CFU/m^3		NF S 90-351	2 classes of rooms
UK	≤35CFU/m^3 rooms at rest, <10 for ultraclean rooms, not to exceed 180CFU/m^3 for more than 5 min		British Standard 52-95-1	
Wales	<10 CFU/m^3		HTM 03-1	
Italy	<180 CFU/m^3		ISPESL 2010	
Russia	<5 CFU/m^1 at OT, <20 CFU/m^1 periphery		GOST R 52539	5 classes of rooms including CFU limitations in ED
South Africa		Class 5, ISO 14644-1	Design of mechanical installations (Core Standards 2006)	

What we covered

1. **Correlation of airborne microbial contamination and HAI/SSI.**
2. Limitations of conventional ventilation in managing airborne threats.
3. How the different ventilation concepts address airborne bioburden in the operating room.
4. The science of Temperature-controlled Air Flow ventilation.
5. Outcomes of performance testing: How the different ventilation systems perform in control of airborne bioburden.



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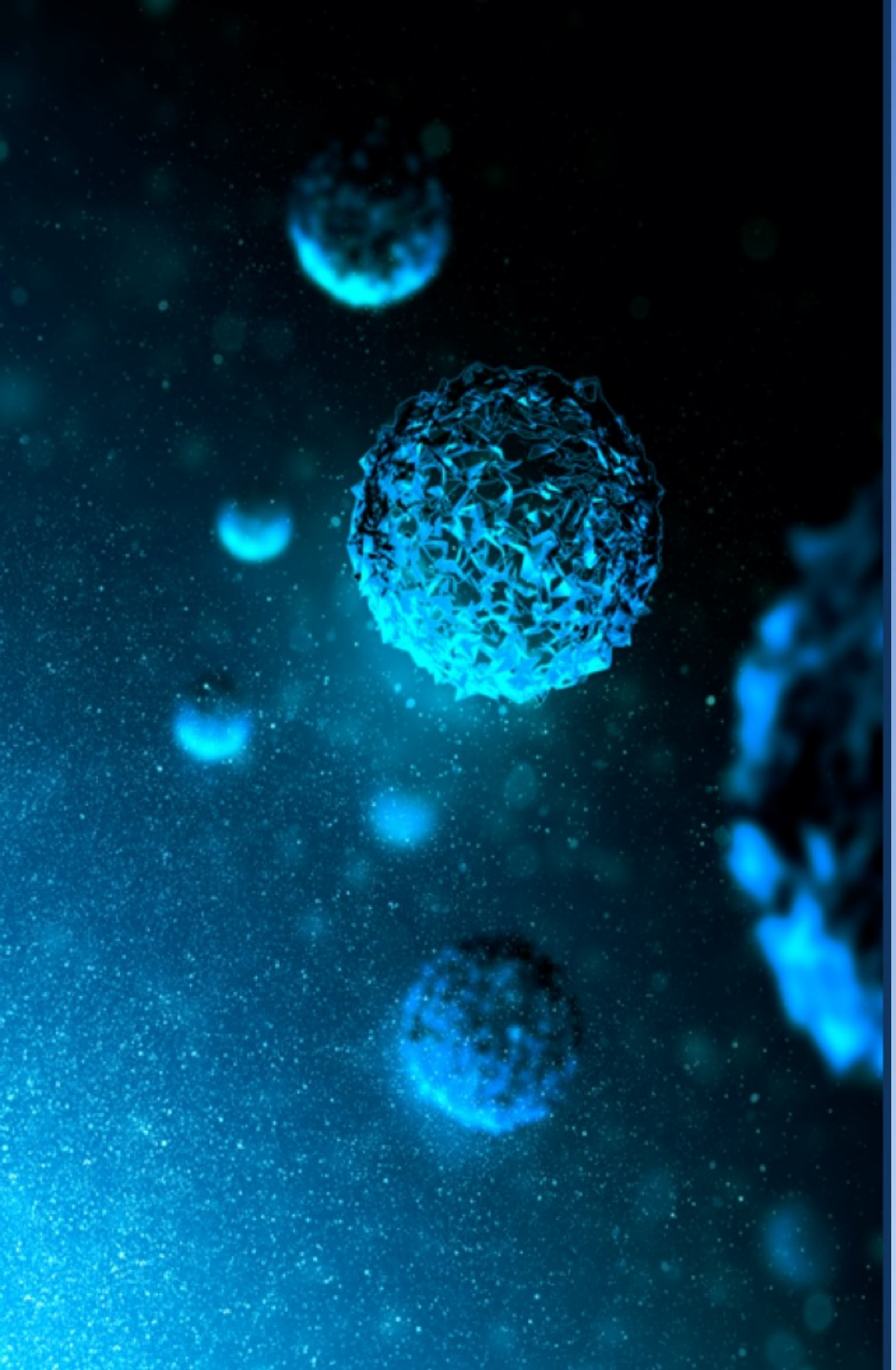
Discussion



Thank You