

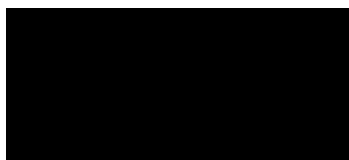
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# CIVE3750

## Aims and Objectives

**Modelling the Impact of Implementing Different Ventilation  
Schemes in a Multi-Bed Hospital Ward: Comparison of  
Analytical and Computational Fluid Dynamic (CFD)  
Methods**

By



Jan 2019

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# 1 INTRODUCTION

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Nosocomial infections also known as Healthcare Acquired Infections (HCAI), are infections that arise in response to either direct medical treatment or from residing in a healthcare setting. Nosocomial infections affect over 4 million people across Europe each year, with approximately 1% of cases resulting in death (GOV.uk, 2016). As expected the issue of nosocomial infections is prevalent in the UK also, 300,000 patients are affected annually, costing an estimated additional £1 billion for the NHS (Mantle, 2015). Nosocomial infections drain NHS resources and decrease patient confidence in their health service. Severity of nosocomial infections ranges from mild bladder infections to potentially fatal respiratory diseases.

Nosocomial infections have troubled patients since records began, however an understanding of common paths of transmission in healthcare facilities has enabled a reduction in their prevalence. Often the transmission is investigated analytically or in a laboratory due to the restrictions of investigations in a hospital environment. Modelling offers great potential to better understand the transmission routes and assess which interventions will be the most beneficial. This project focuses on the coupling between computational fluid dynamic modelling and analytical models to analyse the airborne infection dispersion in healthcare facilities.

## 1.1 TRANSMISSION AND CONTROL OF INFECTION

Pathogens are thought to be transmitted in the environment through three main routes:

- Contact transmission: either by direct or indirect contact with infection
- Airborne transmission: small particles, up to  $5\mu\text{m}$ , are suspended in the air and carried relatively larger distances than droplets
- Droplet transmission: where larger particles are expelled to the air through actions such as, sneezing or coughing, travelling smaller distances than airborne particles

Contact transmission of contaminants can be considered the main route leading to nosocomial infections (Pittet *et al.*, 2006). It was Ignaz Semmelweis, over a century ago who first recognised the importance of hand-washing within healthcare environments, today hand hygiene compliance is a proven effective method of controlling contact transmission, therefore a mechanism to reduce the rate of nosocomial infections (Salama *et al.*, 2013). Many studies are concerned with improving hand washing methods and frequency (Albert and Condie, 1981), and hygiene products to reduce infection spread (Doebbeling *et al.*, 1999). Hand hygiene compliance levels over 80% has been associated with a 48% reduction in Methicillin-resistant *Staphylococcus aureus* (MRSA) transfer: an infection often appearing in patients with an already compromised immune response, which is resistant to most common antibiotics, so requires complex treatment (Marimuthu, Pittet and Harbarth, 2014). Traditional measures to reduce nosocomial infections have focused on preventing contact transmission (Weinstein, 1991). Often nosocomial infections are acquired from an indirect route via the healthcare worker to a susceptible individual after dealing with an infected patient (Goldmann and Larson, 1992). Control measures against nosocomial infections implemented previously have ranged in complexity; recently using alcohol based hand gel reduced hospital infection rates by 5% (Pittet *et al.*, 2016), whilst improving catheter care over 20 years ago reduced urinary tract infections by 32%; in 1975 only 6% of nosocomial infections were thought to be avoided (Haley *et al.*, 1985). Harbarth, Sax and Gastmeier (2003) presented a review determining to what extent nosocomial infections are preventable; currently, up to 30% of all nosocomial infections are thought avoidable in healthcare settings.

Over 100 years ago Flugge investigated how infection is transferred by respiratory droplets typically generated by sneezing and coughing (Flugge, 1987), he showed they did not travel more than 2m before depositing on either a surface or another patient (Eames *et al.*, 2009). Later, Wells (1934) developed a relationship between time to fall to the ground and droplet diameter, aiming to quantify the infective time and rate of the droplets. Further development to quantify the spread via respiratory droplets proved that expelled large droplets could travel as far as to 6m before falling to the ground (Xie *et al.*, 2007). Generating quantified, reliable information helps engineers to develop methods and controls to reduce the transmission.

In contrast to the transmission by respiratory droplets being limited to short distances, airborne transmission considers much smaller particles that can survive in the air for much longer periods of time (Duguid, 1946), sometimes in excess of a week. Ventilation rate has been the focus of many studies relating to the transmission of airborne infections. Riley *et al.* (1962) used guinea pigs to demonstrate that air delivered from a Tuberculosis (TB) ward caused 63 infections amongst susceptible mice, proving tuberculosis is transmitted via airborne particles released from infected patients (Nhs.uk, 2016). Schulman and Kilbourne (1962) used mice; infected mice resided amongst susceptible mice to investigate the transmission from infected sources. Both found the infection rate of the susceptible population was inversely proportional to the ventilation rate (Riley *et al.*, 1962; Schulman and Kilbourne, 1962). This is presented in the Well's-Riley equation (1978) which quantifies the relationship between anticipated infection rates to ventilation rate. Published data reveals, a cough releases approximately 3,000 expelled airborne droplets and as many as 40,000 are emitted when sneezing; all mixing with the internal air (Cole and Cook, 1998; Fernstrom and Goldblatt, 2013). Increasing ventilation rate aims to dilute the concentration of the released particles by replacing the contaminated air with clean air. Filters can also be introduced to capture the infectious particles, with high-efficiency particulate air (HEPA) filters effectively reducing pathogen levels in wards (Araujo, Cabral and Rodrigues, 2008). TB particle concentrations were shown to be reduced by up to 90% by implementing a strategy including both increased ventilation and portable air filters in the room (Miller-Leiden *et al.*, 1996). A rare hospital-based study concluded that workers in general patient rooms with ventilation rates less than 2AC/h were more likely to contract TB (Menzies *et al.*, 2000).

Airflow in buildings is not only concerned with introducing air from the outside into the indoor environment, as air is also transported internally. Where internal airflows are turbulent, the airborne particles are able to travel much further distances (Klettner, Eames and Tang, 2012), therefore are more likely to result in infection. Investigations of internal airflows in hospitals have been completed using tracer gases to monitor the transmission of airborne particles (Gustafson and Nilsson, 1982; Bloch, Hirano and Gould, 1985; Van Hutton, 1990). A systematic review in 2007 reviewed five reliably conclusive cases relating ventilation rate in hospitals and airborne transmission of pathogens (Li *et al.*, 2007). Ventilation systems in hospitals differ from that of other buildings significantly. A minimum of 6AC/h is required in intensive care, (Kaushal, Saini and Gupta, 2004) whilst it is appreciated that increasing ventilation reduces transmission, considerations to cost, appropriateness and patient comfort must be evaluated.

Further research into nosocomial transmission via airborne routes has arisen in response to the recent Severe Acute Respiratory Syndrome (SARS) epidemic in Hong Kong 2002-2003, this is the largest recorded nosocomial outbreak of SARS (Lau *et al.*, 2004): an airborne transmitted virus. From a single infected patient in ward, a total of 1750 cases were identified in the next 3 months, causing 286 deaths (Lee, 2003). This makes evident the importance of reducing airborne transmission. Reviewing the possible causes of the initial epidemic, a Computational Fluid Dynamic (CFD) model determined a reason for rapid spread could have been the result of a 0.5°C temperature difference between the ward and connecting corridor (Zhao *et al.*, 2011). On investigation, the CFD model demonstrated that a two-way airflow pattern had been generated due to the small temperature difference, therefore infectious droplets were carried from the ward to the corridor

and beyond, resulting in the severe transmission of SARS (Zhao *et al.*, 2011). Retrospective investigations demonstrate how CFD models can be manipulated to examine the constantly varying relationship between design factors within internal spaces, developing an obvious limitation to investigating the effect of these factors independently with analytical methods.

Other environmental conditions impact airborne transmission: influenza virus transmission decreases with increasing relative humidity (RH) and with increasing temperatures, evidence confirms transmission ceases at temperatures above 30°C (Lowen *et al.*, 2007). In contrast, Adenovirus, responsible for respiratory infections, exhibits maximum stability at 80% RH (Miller and Artenstain, 1967) and rhinovirus, most prevalently responsible for the common-cold, also exhibited behaviour suggesting a greater infection spread at a higher RH (Karim *et al.*, 1985). The Gumboro virus, evident in chickens, does not exhibit a simple correlation with temperature, but instead reaches a maximum infectious power at 20°C, where it poses much higher risk than when transmitting at either 10°C or 30°C (Zhao *et al.*, 2012). Research into the behaviour of specific strands of airborne infectious pathogens demonstrates the difficulty in designing the environment of a hospital to reduce the transmission, due to the conflicting behaviours of different pathogens. As ventilation will impact the behaviour of different strains of airborne pathogens with the same pattern, ventilation strategies will be investigated as a method for decreasing airborne transmission of pathogens.

## 2 INFECTION RISK MODELS

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### 2.1.1 Analytical Modelling

A transfer analysis, such as the transfer of airborne contaminants can be investigated three ways: experimentally, analytically or by computational analysis. Due to the nature of a health-care environment, it is difficult to collect experimental data of the airborne transmission of contaminants. Utilising real patients to determine the transmission of airborne infections would be unethical, equally it is not possible to take a hospital facility out of action. Modelling of airborne transmission, due to the complexity of influencing factors and the dependence on individual viruses and hosts, is very difficult.

Modelling of airborne contaminants has been traditionally conducted analytically. Wells and Riley (1978) developed an equation to predict the risk of airborne transmitted diseases. This equation predicts the number of new infected cases in a given time by considering: a population containing both infected and susceptible individuals, room and pulmonary ventilation rates, as well as a unit relating infections called quantum (Riley, Murphy and Riley, 1978). Quantum was a concept originally introduced by Wells (1955) alone, this is the dose required to cause a new case of infection and is related to the number of infectious droplets, each pathogen has a unique quantum. Considerable numbers of other analytical models have been developed from the basis of this equation, it is a reputable method for modelling infection risk. However the Wells-Riley equation is limited to the application of a single enclosed space and by two prominent assumptions: first, that there is a uniform spatial distribution of pathogens in a room and second, steady-state conditions; meaning the quantum generation rate and outdoor supply air rate to the room are constant (Sze To and Chao, 2010).

Alternatively, Influenza specifically, has been modelled using regression models (Serfling, 1963) based on seasonal variations, where the number of deaths was modelled. Susceptible-infected-recovered (SIR) models are dynamic in reflecting the response of a population in a cycle of infection and recovery amongst the susceptible individuals (Wu and Zhang, 2018). The Kermack and Mckendrick model is a very simple, early

example of an SIR model (Kermack and McKendrick, 1927), this has been appraised for under-estimating actual infection case numbers (Gani and Swift, 2010). SIR models have been further developed to consider demographics, however are limited by the assumption of the population having equal probabilities (Johnson, 2009). Researchers have favoured modelling utilising the Wells-Riley equation as it can be applied to many known airborne transmitted diseases including: TB (Furuya, Nagamine and Watanabe, 2009) and SARS (Zheng *et al.*, 2016).

Noakes and Sleight (2009) reviewed the application of the Well's-Riley equation to quantify the risk of airborne infection; the original Wells-Riley equation was developed to simulate a random variable relating time to the next incident of infection. This study models the rate of infection risk in a multi-bed ward with different ventilation regimes, exploring how airflow patterns influence infection risk (Noakes and Sleight, 2009). The Wells-Riley equation has been since criticised, when reviewing actual data from infection outbreaks, the distribution of infected cases is related to: source location, airflow pattern and ventilation strategy, none of which are considered (Pica and Bouvier, 2012). Recognising the limitations, other researchers have developed the Wells-Riley equation; Gammaitoni and Nucci, 1997, altered the model for non-steady state conditions. Factors to consider other environmental effects were also included, this reflected workers wearing masks as well as a time dependent factor relating susceptible people present to the quantum. (Gammaitoni and Nucci, 1997). Rudnick and Milton also removed the steady-state limitation of the original Wells-Riley equation by introducing a variable to consider what portion of the room air contained exhaled air (Issarow, Mulder and Wood, 2015). Nevertheless, both of these progressions were still assuming the impossible assumption that pathogens were evenly distributed within the room air. Liao *et al.* (2013) integrated the Wells-Riley equation with a competing risks model to consider the impact of engineering control methods that have been applied to a space, here the reduction in infectious risks were calculated considering implemented control measures such as HEPA filters, UV germicidal irradiation and increased air flow rates.

Implementing analytical approaches are very time consuming and laborious. More recently computational fluid dynamic modelling has been used to model ventilation strategies in hospitals and other flows.

### **2.1.2 Computational Fluid Dynamic Modelling**

Computational fluid dynamic (CFD) modelling has been previously applied to hospitals for a range of studies. Thermal comfort of patients in isolation rooms has been modelled to determine appropriate conditions (Kermani, 2015). Whilst entire hospital layouts have been simulated to investigate the effect of spatial layouts on air distribution (Johanes, Yandi and Atmodiwirjo, 2015).

Studies investigating airborne transmission of pathogens within hospitals using CFD modelling are in less abundance. Airborne transmission of infectious droplets has been modelled for events of coughing and breathing within a hospital environment, to analyse the effectiveness of the ventilation systems (Balocco and Liò, 2010). Hathway (2008) used CFD modelling to investigate the importance of recognising the location of the source to determine infection risk from airborne transmission within a hospital room. Not only release from a patient's mouth was investigated, but also the release from surfaces due to any disruptive activity causing pathogens to become airborne. (Hathway, Noakes and Sleight, 2008). CFD modelling has been used conclusively to prove the early findings of Schulman and Richborne (1962); increased ventilation rates decreased the rate of nosocomial infections within their mice population. CFD shows that increasing the ventilation rate from 2AC/h to 6AC/h decreases the amount of airborne pathogens present by 66% (Gilkeson, Noakes and Khan, 2014).

Mazumdar et al. (2014) recognised the limitations of analytical solutions within their CFD simulation of an airliner cabin. Analytical processes were used to model airborne contaminant transmission at locations far from the source, where steady-state conditions are valid to assume, yet a CFD model was implemented for close locations to account for areas where the steady state assumption would grossly under-predict infection cases (Mazumdar *et al.*, 2014). The models were coupled to produce a holistic model covering all areas.

CFD models can be used to recreate the situations that have been assessed analytically. This process can be used to determine the accuracy and reliability of the analytical model and CFD approach. Confirming the findings from analytical tests by utilising CFD simulations of the same approach can enable vital conclusions for the transmission of airborne pathogens in order to implement changes to hospital ventilation to reduce the nosocomial infections. Here limitations arising from analytical equations can be removed by the parameters set-up on the CFD model.

CFD modelling has been adopted to review different ventilation strategies of a multi-bed ward, highlighting the need to utilise simulation tools to properly understand the influence of airflow patterns (Beggs *et al.*, 2008). A comparison of results derived from analytical solutions and CFD modelling in relation to control measures adopted to reduce nosocomial infection spread exist. UV systems can be implemented to reduce airborne transmission, results from a CFD model were compared to predictions of an analytical solution to evaluate UV devices (Noakes, Beggs and Sleight, 2004). Proving reasonable agreement between derived analytical solutions and CFD model results showcase the capability of utilising CFD models in design and analysis to better understand the indoor environment.

Comparing simulations of a CFD model with the results of the Wells-Riley equation to predict the infection risk from airborne transmission of contaminants would confirm to what extent CFD modelling can be utilised by engineers to design and improve healthcare facilities aiming to reduce the burden of nosocomial infections. Prominent from analysing the SARS outbreak, is the importance of modelling multi-room capacities and analysing the airborne transmission response to indoor conditions holistically. Currently models exist mainly for single occupancy rooms, but unlike the US protocol, the UK practice is to have 4-6 patients in a room. Response behaviour differs greatly from a multi-bed ward to an isolation room, therefore the limited knowledge of airborne transmission in multi-bed wards is hindering the progression to reduce nosocomial infection rates in UK healthcare facilities.

### 3 AIMS AND OBJECTIVES

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Aim:

To compare the spatial distribution of airborne pathogens in multi-bed hospital wards using computational fluid dynamics modelling and analytical analysis, and evaluate the influence of ventilation parameters on infection risk.

Objectives:

1. To evaluate the current knowledge and gaps in understanding on airborne infection and control, particularly to understand:
  - Airborne contaminant transmission and factors affecting this
  - How hospital wards have been developed to reduce airborne transmission of contaminants
  - Ventilation strategies for hospitals
  - How airborne contaminant transmission is modelled analytically
  - How CFD has been applied to a hospital environment
2. To evaluate the methodologies for investigating how airborne contaminants are transported, including comparing advantages and disadvantages of different methods and determining appropriate time constraints and equipment constraints of the available facilities.
3. To develop a test model to investigate the factors affecting transfer of airborne contaminants in a multi-room environment and validate CFD modelling techniques against published data. Validating the test model will confirm the accuracy of CFD modelling and enable this technique to be progressed with.
4. To build a simple, but realistic multi-bed hospital ward model using ANSYS Fluent to simulate dispersion of an airborne contaminant.
5. To investigate how the flow conditions, source location and inlet and outlet positions affect the spatial distribution of airborne contaminant concentration.
6. To compare the results acquired by CFD simulations with that predicted by analytical models, and consider the implications for accuracy of infection risk modelling.

## 4 METHODOLOGY

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Existing knowledge will be collected and consulted this develops what is already known regarding the airborne transmission of contaminants. The method outlined below will then proceed to collect results of a format that can be compared to an analytical model.

### 4.1.1 Test Model Validation

Test model validation aims to prove that the computer modelling technique implemented will produce reliable results. In order to validate the CFD model it must be compared to known existing data to confirm the accuracy. As limited information exists regarding CFD models of airborne contaminant transmission in hospitals, the test model will compare indoor airflow velocities determined by a CFD model to experimental data.

This test model, previously completed by Tian et al. (2006) is used to determine air velocities, these are then compared to experimental data from Posner et al. (2003) in order to validate the computer model. Recreating the conditions and set-up investigated by Posner et al. offers a validation for the model. If/when the model simulation results for air velocity match the experimental data from Posner et al. the model has been validated and a similar approach can be applied to construct the model of the hospital ward.

### 4.1.2 Constructing a Hospital Ward Model

Initially the geometry of the hospital ward must be set up, the geometry must reflect the situation that the analytical solutions represent so the results can be compared. This investigation is based on a multi-bed ward consisting of three zones containing four beds each and the corridor linking them shall also be modelled. As CFD models iterate a very detailed analysis, overcomplicating the geometry can lead to unwelcome problems, therefore the hospital ward will be simplified to reduce the complexity of the model.

Obtaining useful results from a simulation is often reflected by the appropriateness of the mesh size, the hospital ward will require meshing. Meshing the geometry is a process that divides the space into a large number of smaller elements, the concepts utilised by CFD are solved for each element to map the whole problem.

After the geometry and mesh of the model have been finalised, the properties of the problem are applied to the model. Applying these properties allow the CFD model to correctly apply the appropriate flow physics for the problem. Carbon dioxide gas (CO<sub>2</sub>) will be used as a tracer gas for these simulations, it will act as a carrier representing the realistic case of airborne pathogens being transmitted via CO<sub>2</sub> movement. CFD modelling software, ANSYS Fluent, has pre-loaded properties for CO<sub>2</sub> as a fluid so will produce accurate results. Each simulation will utilise the same hospital ward model, with each bay modelled to contain six patients all breathing at the same rate of 0.01m<sup>3</sup>/min, one of whom in the first bay is infected with each other patient being susceptible.

Boundary conditions must be applied to mimic the realistic situation. Particularly important for this investigation; any inlet and outlet positions must be entered in the model and the conditions at these locations including air velocity and pressure.

### 4.1.3 Model Simulation

Different test cases will be analysed to determine the effect of changing the inlet and outlet positions and the air flow parameters. Therefore, each simulation will involve adjusting the inlet and outlet flow positions to represent different ventilation strategies in hospital wards. Results will be obtained for each different strategy,



extracted data will display the concentration of pathogen carrying CO<sub>2</sub> present in each location of the model, enabling the infectious particles to be tracked.

#### **4.1.4 Analysis of results**

Results collected from CFD simulations will be compared to the results established analytically for the same room geometry and applied conditions. An existing spreadsheet which implements the Wells-Riley equation to determine the spatially varying infection risk within a multi-bed hospital ward will be used to compare to the CFD model results. Currently the existing spreadsheet has been used to determine infection risk implementing the Wells-Riley equation, however this will not be a variable that can be extracted from the CFD simulations. Therefore data from the existing spreadsheet will require manipulation before reliable comparisons of the two methods can be drawn. Comparing the analytical and computational analysis will determine the accuracy and reliability of measuring airborne contaminant transmission with CFD modelling.

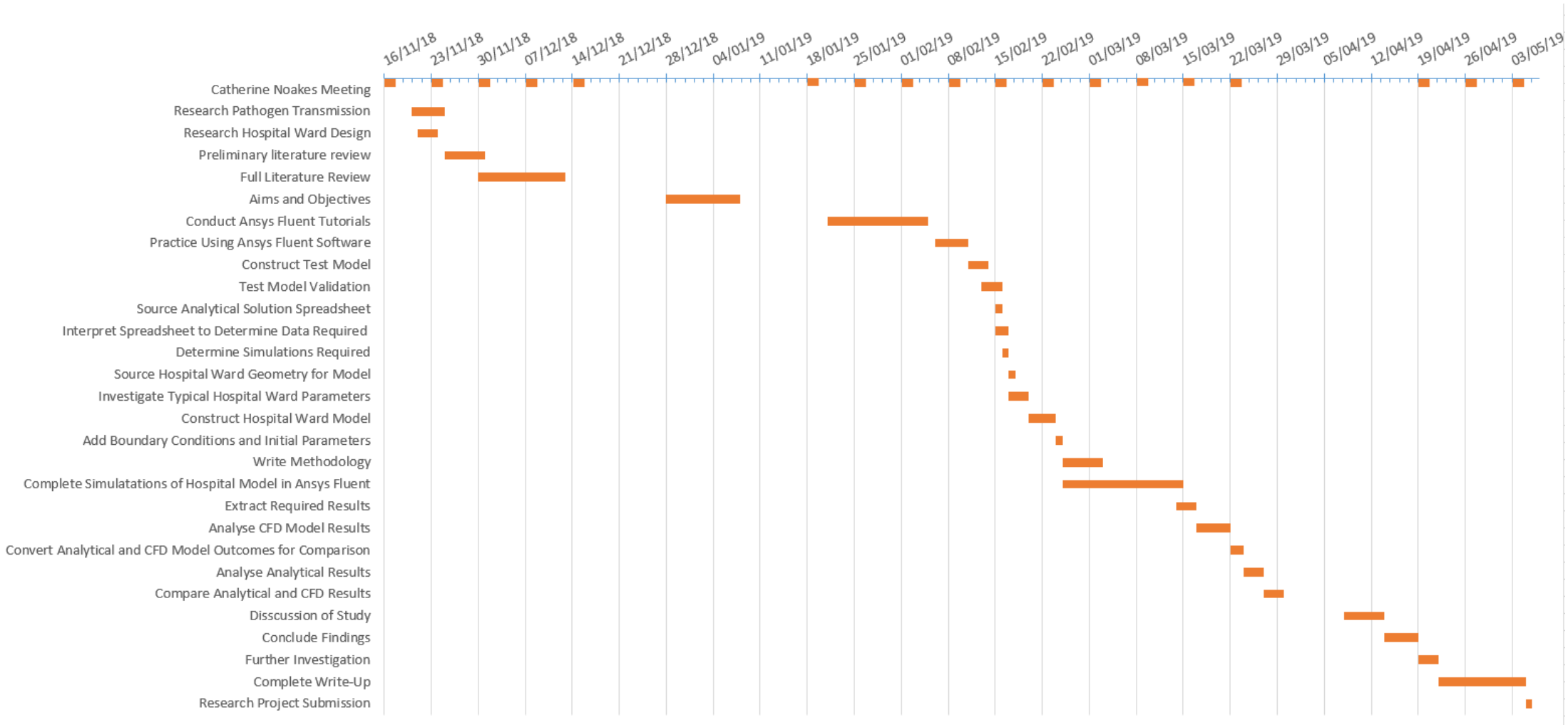
## **5 RISK ASSESSMENT AND ETHICS APPROVAL**

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This independent research project will be a desk-based study that will involve critically analysing existing research and constructing a unique model to conduct computer simulations of a hospital ward. As this is a desk-based study there is no risk assessment nor ethical approval required due to no foreseen risks and no requirement to seek ethical approval. A completed ethics form is attached for completeness.

## 6 WORK SCHEDULE

The following Gantt chart demonstrates the tasks required to be completed for this study.



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## 8 ETHICS FORM

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This form should be completed by the student and passed to the supervisor prior to a review of the possible ethical implications of the proposed dissertation or project.

**No primary data collection can be undertaken before the supervisor has approved the plan.**

If, following review of this form, amendments to the proposals are agreed to be necessary, the student should provide the supervisor with an amended version for endorsement.

1. What are the objectives of the dissertation / research project?

To compare the spatial distribution of airborne pathogens in multi-bed hospital wards using computational fluid dynamics modelling and analytical analysis, and evaluate the influence of ventilation parameters on infection risk.

2. Does the research involve *NHS patients, resources or staff*? NO

3. Do you intend to collect *primary data* from human subjects or data that are identifiable with individuals? (This includes, for example, questionnaires and interviews.) NO

If you do not intend to collect such primary data then please go to question 14.

If you do intend to collect such primary data then please respond to ALL the questions 4 through 13. If you feel a question does not apply then please respond with n/a (for not applicable).

4. What is the *purpose* of the primary data in the dissertation / research project?

5. What is/are the *survey population(s)*?

6. How big is the *sample* for each of the survey populations and how was this sample arrived at?

7. How will respondents be *selected and recruited*?

8. What steps are proposed to ensure that the requirements of *informed consent* will be met for those taking part in the research? If an Information Sheet for participants is to be used, please attach it to this form. If not, please explain how you will be able to demonstrate that informed consent has been gained from participants.

9. How will *data* be *collected* from each of the sample groups?

10. How will *data* be *stored* and what will happen to the data at the end of the research?

11. How will *confidentiality* be assured for respondents?

12. What steps are proposed to safeguard the *anonymity* of the respondents?

13. Are there any *risks* (physical or other, including reputational) *to respondents* that may result from taking part in this research? YES / NO (please circle).

If YES, please specify and state what measures are proposed to deal with these risks.

14. Are there any *risks* (physical or other, including reputational) *to the researcher or to the University* that may result from conducting this research? NO

If YES, please specify and state what measures are proposed to manage these risks.

15. Will any *data* be *obtained from a company or other organisation*. NO (please circle) For example, information provided by an employer or its employees.

If NO, then please go to question 18.

16. What steps are proposed to ensure that the requirements of *informed consent* will be met for that organisation? How will *confidentiality* be assured for the organisation?
17. Does the organisation have its own ethics procedure relating to the research you intend to carry out? YES / NO (please circle).

If YES, the University will require written evidence from the organisation that they have approved the research.

18. Will the proposed research involve any of the following (please put a  $\surd$  next to 'yes' or 'no'; consult your supervisor if you are unsure):

- |   |     |                          |    |                                     |
|---|-----|--------------------------|----|-------------------------------------|
| • Vulnerable groups (e.g. children) ?       | YES | <input type="checkbox"/> | NO | <input checked="" type="checkbox"/> |
| • Particularly sensitive topics ?           | YES | <input type="checkbox"/> | NO | <input checked="" type="checkbox"/> |
| • Access to respondents via 'gatekeepers' ? | YES | <input type="checkbox"/> | NO | <input checked="" type="checkbox"/> |
| • Use of deception ?                        | YES | <input type="checkbox"/> | NO | <input checked="" type="checkbox"/> |
| • Access to confidential personal data ?    | YES | <input type="checkbox"/> | NO | <input checked="" type="checkbox"/> |
| • Psychological stress, anxiety etc ?       | YES | <input type="checkbox"/> | NO | <input checked="" type="checkbox"/> |
| • Intrusive interventions ?                 | YES | <input type="checkbox"/> | NO | <input checked="" type="checkbox"/> |

19. Are there any other ethical issues that may arise from the proposed research? NO

Please print the name of:

I/We grant Ethical Approval

student \_\_\_\_\_ supervisor \_\_\_\_\_

Signed:

(student) \_\_\_\_\_ (supervisor) \_\_\_\_\_

Date \_\_\_\_\_ Date \_\_\_\_\_

## AMENDMENTS

If you need to make changes please ensure you have permission before the primary data collection. If there are major changes, fill in a new form if that will make it easier for everyone. If there are minor changes then fill in the amendments (next page) and get them signed before the primary data collection begins.