HKU Med LKS Faculty of Medicine
The University of Hong Kong
香港大學李嘉誠醫學院

PATIENT INFORMATION SHEET AND CONSENT FORM

STUDY TITLE

Antibiotic stewardship through CRP-guided antibiotic treatment for patients with Acute Exacerbation of Chronic Obstructive Pulmonary Disease (AECOPD)

Version 1.0

Date

8 July 2021

Patient Information Sheet

Study Title: **Antibiotic stewardship through CRP-guided antibiotic treatment for patients with Acute Exacerbation of Chronic Obstructive Pulmonary Disease (AECOPD)**

Investigator: Dr. WAI Ka Chung, Abraham (Emergency Medicine Unit)

Institution: The University of Hong Kong

You are being invited to take part in a research study led by The University of Hong Kong. Before you decide whether you want to participate, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish.

Thank you for reading this.

1. What is the purpose of this research?

You have presented to the hospital with symptoms and signs suggestive of Acute Exacerbation of Chronic Obstructive Pulmonary Disease (AECOPD). We are conducting a study to investigate whether C-reactive protein (CRP) guided antibiotic treatment for managing AECOPD in adult patients attending Emergency Departments shortens the antibiotic use, maintaining COPD health status as good as usual care.

We would greatly appreciate it if you are willing to participate in our research study.

2. Why have you been invited?

You have presented to the hospital with symptoms and signs suggestive of Acute Exacerbation of Chronic Obstructive Pulmonary Disease (AECOPD). Your doctor will assess your condition and eligibility for the current study.

3. Do you have to take part?

You <u>are not obliged</u> to take part. It is up to you to decide whether or not to take part. If you do decide to take part, we will describe the study and ask you to sign a consent form. If you decide not to take part, you do not have to explain your reason and it will not affect your medical treatment or legal rights.

You are free to withdraw your consent at any time, without giving a reason, even after signing the consent form. Any unused data will be destroyed. Any results that have been used prior to the withdrawal of consent will continue to be used in this study.

4. What will happen to me if I take part?

A doctor will check whether you are suitable for the study. Other doctors and nurses will also assess you as usual. If you agree to the study and are suitable then you will be taken a few samples. These samples include a sputum sample, a throat swab sample (for bacterial culture), and a nasopharyngeal swab (for the respiratory virus – pneumonia panel). The attending

physician will assess and record the sputum colour. You will then be interviewed for two questionnaires to investigate your situation of COPD and life quality. After these, you will be randomised to one of two study groups:

- Group 1 Intervention group.
- Group 2 Control group.

Group 1. If you are randomly allocated to **Group 1** you will receive standard usual care (following GOLD initiative, including bronchodilator, and systemic steroid). Your doctor will be suggested to test you for serum CRP daily during your stay in the hospital according to clinical need. Antibiotic prescription is considered when CRP >5mg/dL. Once CRP has declined to <5mg/dL and you are afebrile for the past 48 hours, antibiotic discontinuation will be recommended to consider.

Group 2. If you are randomly allocated to **Group 2** you will also receive standard usual care. No study-related CRP would be measured.

Follow Up

You will be followed up by questionnaires for the first and third weeks, as well as the sixth month after your participation. You will be followed up by questionnaires and will be taken a few samples. These samples include a sputum sample, a throat swab sample.

5. Will I be paid anything for taking part?

Any data collected will be treated as a gift to The University. You will not benefit financially from taking part in this study or the future should this research lead to the development of a new treatment.

6. What will my data be used for?

We will use the data in this study to see if CRP-guided antibiotic treatment, compared with usual care, could lead to shorter antibiotic duration without negatively impact on clinical COPD-health status.

Your participation in this study is entirely voluntary. All information obtained in this study is kept strictly confidential. You may withdraw consent at any time and request that we don't use your data. All publications from this study will only show aggregated results and will not release your personal identity.

If you want to take part in the study, all data will be kept and will be used only for the purposes of research. With your consent, anonymised data may be used for future studies on respiratory emergencies. All data will be kept confidential.

7. What are the possible benefits of taking part?

Your contribution will help us to investigate whether CRP-guided antibiotic treatment can lead to shorter antibiotic duration without negatively impact on clinical COPD-health status than current care. The information that we get from this study will help us to improve treatment for patients presenting with AECOPD in the future. You will be monitored more closely and will be followed up for longer. Information from this study will not only benefit you but also future patients with AECOPD in Hong Kong.

8. What are the possible risks of taking part?

We make every effort to ensure that the treatment you receive is safe. The collection of blood samples will involve minimal discomfort and is no different from usual care. It will only take a short amount of time. All of the study procedures will be carried out by trained clinical staff. There are no known additional risks arising from your participation in the study.

9. Will my taking part in this study be kept confidential?

All identifiable information collected about you during the study will be kept strictly confidential in accordance with the laws of the Hong Kong Special Administrative Region and, in particular, the Personal Data (Privacy) Ordinance, Cap 486. Your name, address, or any other identifying information will not be passed on to anyone and your data will be assigned an anonymous identification code. You will not be identified in any published study results. Only the University research team will have access to the information that can identify you and link you to your data.

You have the rights of access to personal data and publicly available study results, if and when needed. Under the laws of Hong Kong (in particular the Personal Data (Privacy) Ordinance, Cap 486), you benefit or may benefit from rights for the protection of the confidentiality of your personal data, such as those regarding the collection, custody, retention, management, control, use (including analysis or comparison), transfer in or out of Hong Kong, non-disclosure, erasure and/or in any way dealing with or disposing of any of your personal data in or for this study. For any query, you should consult the Privacy Commissioner for Personal Data or her office (Tel No. 2827 2827) as to the proper monitoring or supervision of your personal data protection so that your full awareness and understanding of the significance of compliance with the law governing privacy data is assured.

By consenting to participate in this study, you expressly authorise:

- the principal investigator and his research team and the ethics committee responsible for overseeing this study to get access to, to use, and to retain your personal data for the purposes and in the manner described in this informed consent process; and
- the relevant government agencies (e.g. the Hong Kong Department of Health) to get access to your personal data to check and verify the integrity of study data and assessing compliance with the study protocol and relevant requirements.

10. What will happen to the results of the study?

We hope to use the results from this study to inform larger studies. It is our intention to publish the results of this study in academic journals and present findings at conferences. Under no conditions would any personal data be released. Furthermore, all data collected in this study may be analysed in other related studies that we may conduct in the future.

11. Who is organising and funding this research?

The research is organised by Dr. WAI Ka Chung, Abraham from the Emergency Medicine Unit at the LKS Faculty of Medicine at The University of Hong Kong and is being carried out using Government research funds.

12. Further information and contact details

If you have further questions about this study and/or your participation, you are most welcome to contact the Principal Investigator – Dr. WAI Ka Chung, Abraham, (Email: awai@hku.hk or Phone: +852 3917-9859).

This study has been approved by the Institutional Review Board of The University of Hong Kong/ Hospital Authority Hong Kong West Cluster (HKU/HA HKW IRB). If you have questions about your rights of being a study subject, please contact the Institutional Review Board of The University of Hong Kong / Hospital Authority Hong Kong West Cluster (HKU/HA HKW IRB) secretary (Tel: +852 2255-4086).

Study Number: ☐ ☐ ☐ ☐ ☐ ☐

Consent form

Title of Study: Antibiotic stewardship through CRP-guided antibiotic treatment for patients with Acute Exacerbation of Chronic Obstructive Pulmonary Disease (AECOPD)

Name of Researcher: Dr. WAI Ka Chung, Abraham

	Please initial box
1. I confirm that I have read and understood the information sheet dated _____/_____/____ for the above study and have had the opportunity to ask questions.	☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	☐
3. I understand that sections of any my medical notes may be looked at by responsible individuals from the research team or from regulatory authorities where it is relevant to my taking part in the research. I give permission for these individuals to have access to my records.	☐
4. I understand that the data collected in this study might be stored by the researchers for future studies on respiratory emergencies. I give permission to the researchers of this study at the University of Hong Kong or their research collaborators at other academic institutions to perform these tests on my samples.	☐
5. I agree to take part in the above study.	☐

Name of Patient/ Legal representative	Date	Signature
Name of Witness (if applicable)	Date	Signature
Name of Doctor	Date	Signature

Copies to:

- Patient/Subject
- Researcher's File
- Hospital Record