**愛媛大学医学部医学科　　総合問題（2021 年度）**　　**参考例**

**120 分**

問題 1.

次の文章を読み、設問に答えなさい。なお「*」の付いた箇所は本文の後に語注があるので参考にしなさい。

Hope for an effective and inexpensive treatment for ① the deadly condition sepsis* has dimmed following results of a major new study.

Researchers had hoped that a simple treatment involving infusions* of vitamin C, vitamin B1 and steroids* would work against a disease that kills an estimated 270,000 people each year in the United States and 11 million globally. Sepsis, or blood poisoning, occurs when the body overreacts* to infection*. It leads to leaky blood vessels, which can cause multiple organ failure.

Excitement about this treatment took off in early 2017, when a well-regarded physician and researcher in Norfolk, Va., Dr. Paul Marik, reported that he had remarkable results treating his sepsis patients using this combination of agents. Some doctors in ICUs* started using the method immediately, based on ② those early results. Many others said they wanted to wait for results of a more carefully controlled study.

(a) The largest scientific study published to date has now reported its findings. It finds no benefit at all from the "Marik cocktail." It involved more than 200 patients in Australia, New Zealand and Brazil. Results were presented Friday at a meeting in Belfast, Northern Ireland, and were published online Friday in JAMA, the journal of the American Medical Association.

③ Dr. Rinaldo Bellomo, at Austin Hospital and Monash University in Melbourne, Australia, led the research team. He decided to study the treatment because sepsis takes such a large toll - it's a leading cause of death in hospitals - and treatment options are

limited. There's no effective drug, though aggressive use of antibiotics* and careful care in the ICU can help.

"People latch* on to promising interventions* because of that frustration," be tells NPR*. "And it's understandable. But, you know, the view from here is that we shouldn't substitute hope for evidence.

His evidence does not support those who believe the vitamin C treatment is effective.

"It is discouraging," says ④ Dr. Craig Coopersmith, interim* director of the Emory Critical Care Center at Emory University. "Right now, sepsis is the number three cause of death in the United States and the number one or two cause of death in the world."

Coopersmith says the results don't slam the door on the treatment entirely - there's still some chance that it has a modest effect on overall survival, he says, but the study didn't involve enough patients to answer that question. The study found no effect on short-term survival or improvement in certain clinical markers of disease.

"I don't think we can yet say that there is no impact," Coopersmith says. "I think we could say that the jury is still out on that."

He assumes that (b) doctors who are inclined toward using the treatment will continue to do so, at least for now, while those who adopted a wait-and-see approach are sticking with that.

Indeed, Marik, who remains a strong proponent* of this approach, rejects the findings of the study. He tells NPR that by his reckoning*, patients in the study received treatment far too late in the course of their disease. "It's like giving it to a patient who's dead." he says.

Marik, at Easter Virginia Medical School, gives his patients the vitamin C infusion as quickly as he recognizes signs of sepsis. ⑤ That is impossible to do in a study in which participants must be enrolled* in a study and then randomized* into one of the two comparison groups before treatment can begin.

"⑥ The question is, why does this study not replicate* real-life experience and the experience of hundreds of doctors around the world?" he asks.

Marik says in his experience, the treatment is only effective if given within six hours after someone has suspected sepsis. At the meeting in Belfast, Dr. Tomoko Fuji, on the study research team at Monash University, said they provided treatment an average of 12 hours after patients arrived in the ICU. Patients came from a variety of locations, including the emergency room, and she said they have no information about how long they had been septic before arriving at the ICU.

Coopersmith is part of a larger study - involving 501 patients - that has also put the vitamin C protocol* to the test. That research group has completed collecting data and is now in the process of analyzing the results and preparing a publication. A second group,

coordinated out of Beth Israel Deaconess Medical Center, also studied the protocol among a group of about 200 patients.

Findings from those studies should help doctors and researchers come to a more definitive* conclusion, says Bellomo in Australia. "I think that will be really good, because we would have a much larger body of evidence. I hope by the end of 2020 to provide more detailed views of what happens with this kind of intervention."

(803 字)

出典 : Richard Harris, Vitamin Treatment For Sepsis Fails In Large Trial (Health News From NPR, January 17,2020)より抜粋、一部改変

[語注〕 sepsis 敗血症、infusion 点滴、 steroid ステロイド、 overreact 過剰反応する、infection 感染、 ICU 集中治療室、 antibiotics 抗生物質、 latch (on to) すがりつく、intervention 介入、 NPR 放送局の名称 (National Public Radio)、 interim 暫定の、proponent 支持者、 reckoning 考え、 enroll 参加登録をする、 randomize 無作為に分ける、 replicate 再現する、 protocol 治療手順、治療法 definitive 決定的な

問 1. 下線部①がどのようなものであるかを最も的確に説明している一文を本文中からそのまま英語で抜き出しなさい。

問 2. 下線部 2 はどのようなことを指しているか。50 字以内の日本語で答えなさい。

問 3. 下線部 3 の D, Rinaldo Bellomo が下線部 (a) の研究を行った動機は何か。80 字以内の日本 語で答えなさい。

問 4. 下線部金の Dr. Craig Coopersmith は下線部(a) の研究結果をどのように捉えているか。 90 字以内の日本語で答えなさい。

問 5. 下線部⑤の That に関して、
(ア) 具体的に何を指すかを日本語で答えなさい。

(イ) このことがなぜ本研究のような臨床研究で不可能なのかを日本語で答えなさい。

問 6.　下線部⑥の The question に関して、
（ア）どのような疑問かを具体的に日本語で答えなさい。

（イ）この疑問への答として、どのようなことが考えられるか。Marik 医師の考えを含め、 150 字以内の日本語で答えなさい。なお、Marik は片仮名でマリクと書きなさい。

問 7.　下線部(6)は、下線部（a)の研究結果が公表された前と後で、医師の治療方針は変わらないであろうとする推察を述べている。確立した治療方法のない疾患において、効果が疑問視される治療法を行うことについて、あなたの意見を 250 字以内の日本語で書きなさい。なお、問題 2 の「 DECLARATION OF HELSINKI」の内容を参考にしてもよい。

問題 2.

次の文章は World Medical Association が作成した「DECLARATION OF HELSINKI」 の全文である。この文章を参考にして、以下の設問に答えなさい。なお「*」の付いた箇所は本文の後に語注があるので参考にしなさい。

## Preamble*

1. The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data.

The Declaration is intended to be read as a whole and each of its constituent paragraphs should be applied with consideration of all other relevant paragraphs.

2. Consistent with the mandate* of the WMA, the Declaration is addressed primarily to physicians. The WMA encourages others who are involved in medical research involving human subjects to adopt these principles.

## General Principles

3. The Declaration of Geneva of the WMA binds the physician with the words, "The health of my patient will be my first consideration, "and the International Code of Medical Ethics declares that, "A physician shall act in the patient's best interest when providing medical care."

4. It is the duty of the physician to promote and safeguard the health, well-being and rights of patients, including those who are involved in medical research. The physician's knowledge and conscience are dedicated to the fulfilment* of this duty.

5. Medical progress is based on research that ultimately must include studies involving human subjects.

6. The primary purpose of medical research involving human subjects is to understand the

causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions (methods, procedures and treatments). Even the best proven interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility and quality.

7. Medical research is subject to ethical standards that promote and ensure respect for all human subjects and protect their health and rights.

8. While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence* over the rights and interests of individual research subjects.

9. It is the duty of physicians who are involved in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects. The responsibility for the protection of research subjects must always rest with the physician or other health care professionals and never with the research subjects, even though they have given consent.

10. Physicians must consider the ethical, legal and regulatory norms and standards for research involving human subjects in their own countries as well as applicable international norms and standards. No national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for research subjects set forth in this Declaration.

11. Medical research should be conducted in a manner that minimizes possible harm to the environment.

12. Medical research involving human subjects must be conducted only by individuals with the appropriate ethics and scientific education, training and qualifications. Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional.

13. Groups that are underrepresented* in medical research should be provided appropriate access to participation in research.

14. Physicians who combine medical research with medical care should involve their patients in research only to the extent that this is justified by its potential preventive,

diagnostic or therapeutic value and if the physician has good reason to believe that participation in the research study will not adversely affect the health of the patients who serve as research subjects.

15. Appropriate compensation and treatment for subjects who are harmed as a result of participating in research must be ensured.

## Risks. Burdens and Benefits

16. In medical practice and in medical research, most interventions involve risks and burdens.

Medical research involving human subjects may only be conducted if the importance of the objective outweighs* the risks and burdens to the research subjects.

17. All medical research involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and groups involved in the research in comparison with foreseeable benefits to them and to other individuals or groups affected by the condition under investigation.

Measures to minimize the risks must be implemented. The risks must be continuously monitored, assessed and documented by the researcher.

18. Physicians may not be involved in a research study involving human subjects unless they are confident that the risks have been adequately assessed and can be satisfactorily managed.

When the risks are found to outweigh the potential benefits or when there is conclusive proof of definitive* outcomes, physicians must assess whether to continue, modify or immediately stop the study.

## Vulnerable Groups and Individuals

19. Some groups and individuals are particularly vulnerable and may have an increased likelihood of being wronged or of incurring* additional harm.

All vulnerable groups and individuals should receive specifically considered protection

20. Medical research with a vulnerable group is only justified if the research is responsive to the health needs or priorities of this group and the research cannot be carried out in a non-vulnerable group. In addition, this group should stand to benefit from the knowledge, practices or interventions that result from the research.

## Scientific Requirements and Research Protocols*

21. Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and adequate laboratory and, as appropriate, animal experimentation. The welfare of animals used for research must be respected.

22. The design and performance of each research study involving human subjects must be clearly described and justified in a research protocol.

The protocol should contain a statement of the ethical considerations involved and should indicate how the principles in this Declaration have been addressed. The protocol should include information regarding funding, sponsors, institutional affiliations*, potential conflicts of interest, incentives for subjects and information regarding provisions for treating and/or compensating subjects who are harmed as a consequence of participation in the research study.

In clinical trials, the protocol must also describe appropriate arrangements for post-trial provisions.

## Research Ethics Committees

23. The research protocol must be submitted for consideration, comment, guidance and approval to the concerned research ethics committee before the study begins. This committee must be transparent in its functioning, must be independent of the researcher, the sponsor and any other undue* influence and must be duly qualified. It must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards but these must not be allowed to reduce or eliminate any of the protections for research subjects set forth in this Declaration.

The committee must have the right to monitor ongoing studies. The researcher must provide monitoring information to the committee, especially information about any serious adverse events. No amendment to the protocol may be made without consideration and approval by the committee. After the end of the study, the researchers must submit a final report to the committee containing a summary of the study's findings and conclusions.

## Privacy and Confidentiality

24. Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information.

## Informed Consent

25. Participation by individuals capable of giving informed consent as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no individual capable of giving informed consent may be enrolled in a research study unless he or she freely agrees.

26. In medical research involving human subjects capable of giving informed consent, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail*, post-study provisions and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal*. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information.
After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's freely-given informed consent, preferably* in writing. If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed.

All medical research subjects should be given the option of being informed about the general outcome and results of the study.

27. When socking informed consent for participation in a research study the physician must be particularly cautious if the potential subject is in a dependent relationship with the physician or may consent under duress*. In such situations the informed consent must be

sought by an appropriately qualified individual who is completely independent of this relationship.

28. For a potential research subject who is incapable of giving informed consent, the physician must seek informed consent from the legally authorized representative. These individuals must not be included in a research study that has no likelihood of benefit for them unless it is intended to promote the health of the group represented by the potential subject, the research cannot instead be performed with persons capable of providing informed consent, and the research entails only minimal risk and minimal burden.

29. When a potential research subject who is deemed incapable of giving informed consent is able to give assent* to decisions about participation in research, the physician must seek that assent in addition to the consent of the legally authorized representative. The potential subject's dissent* should be respected.

30. Research involving subjects who are physically or mentally incapable of giving consent, for example, unconscious patients, may be done only if the physical or mental condition that prevents giving informed consent is a necessary characteristic of the research group. In such circumstances the physician must seek informed consent from the legally authorized representative. If no such representative is available and if the research cannot be delayed, the study may proceed without informed consent provided that the specific reasons for involving subjects with a condition that renders them unable to give informed consent have been stated in the research protocol and the study has been approved by a research ethics committee Consent to remain in the research must be obtained as soon as possible from the subject or a legally authorized representative.

31. The physician must fully inform the patient which aspects of their care are related to the research. The refusal of a patient to participate in a study or the patient's decision to withdraw from the study must never adversely affect the patient-physician relationship.

32. For medical research using identifiable human material or data, such as research on material or data contained in biobanks* or similar repositories*, physicians must seek informed consent for its collection, storage and/or reuse. There may be exceptional situations where consent would be impossible or impracticable* to obtain for such research. In such situations the research may be done only after consideration and approval of a research ethics committee.

## Use of Placebo*

33. The benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best proven intervention(s), except in the following circumstances:

Where no proven intervention exists, the use of placebo, or no intervention, is acceptable; or

Where for compelling and scientifically sound methodological* reasons the use of any intervention less effective than the best proven one, the use of placebo, or no intervention is necessary to determine the efficacy* or safety of an intervention

and the patients who receive any intervention less effective than the best proven one, placebo, or no intervention will not be subject to additional risks of serious or irreversible harm as A result of not receiving the best proven intervention.

Extreme care must be taken to avoid abuse of this option.

## Post-Trial Provisions

34. In advance of a clinical trial, sponsors, researchers and host country governments should make provisions for post-trial access for all participants who still need an intervention identified as beneficial in the trial.
This information must also be disclosed to participants during the informed consent process.

## Research Registration and Publication and Dissemination* of Results

35. Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject.

36. Researchers, authors, sponsors, editors and publishers all have ethical obligations with regard to the publication and dissemination of the results of research. Researchers have a duty to make publicly available the results of their research on human subjects and are accountable* for the completeness and accuracy of their reports. All parties should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results must be published or otherwise made publicly available.
Sources of funding, institutional affiliations and conflicts of interest must be declared in the publication.

Reports of research not in accordance with the principles of this Declaration should not be accepted for publication.

Unproven Interventions in Clinical Practice

37. In the treatment of an individual patient, where proven interventions do not exist or other known interventions have been ineffective, the physician, after seeking expert advice, with informed consent from the patient or a legally authorized representative, may use an unproven intervention if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating* suffering. This intervention should subsequently be made the object of research, designed to evaluate its safety and efficacy. In all cases, new information must be recorded and, where appropriate, made publicly available.

(2240 字)

出典 : DECLARATION OF HELSINKI. Amended by the 64th WMA General Assembly, October 2013 より、一部改変

［語注］ preamble 序文、 mandate 権限、 fulfilment 成就、 precedence 先行、 underrepresented 取り上げられることの少ない、 outweigh 上回る、 definitive 決定的な、 incurring 被害を受ける、 protocol 実施要綱、 affiliation 関係のある組織、 undue 過度の、 entail 伴う、 reprisal 報復、 preferably 望ましくは、duress 強要、 assent 同意、 dissent 不同意、 biobank 生体試料を研究目的で保管する機関、 repository 保管場所、 impracticable 実行不可能な、 placebo 偽薬、 methodological 方法論の、 efficacy 効能、 irreversible 回復不能な、 dissemination 普及、 accountable 説明する義務がある、 alleviate 緩和する

問 1. 以下の事例 1 で、主治医は、臨床研究に参加していただくために、誰に何を説明し、誰から 同意を得るべきか？「DECLARATION OF HELSINKI」を参考にして、あなたの考えを 250 字以内の日本語で答えなさい。

事例 1: 研究者グループが難病を根治できる可能性のある薬剤 A を発見した。しかし、薬剤 A は生 存期間を短縮する副作用が起こる可能性がある。難病である 12 歳の B 子を持

つ親がこの薬剤の ニュースを聞き、B 子に薬剤 A の話をしたところ、B 子は臨床研究に参加したいと言った。親は薬 剤 A の臨床研究を実施する病院を訪れ、「難病である B 子が、薬剤 A の臨床研究への参加を希望 している」と相談した。

問 2.　以下の事例 2 で、研究者グループが行おうとしている臨床研究について、「DECLARATION OF HELSINKI」を参考にして、あなたの考えを 200 語程度の英語で答えなさい。

事例 2:　研究者グループは、心疾患の原因究明を目的として、検査の際に通常より多くの心筋組織を採取して、検査の残りを研究材料にする計画をたてた。通常より多くの心筋組織を採取することによって、現在の患者の病状をさらに悪化させる可能性があるが、研究のために必要であると研究グループは考えた。