



Clinical Research on COVID-19 in Japan

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Research for clinical response method development for emerging and re-emerging respiratory infections such as Middle East Respiratory Syndrome (MERS)

(Number:H27-新興- 指定- 006 Period: H27—28)

Observation to South Korea (Korean CDC, Seoul University Hospital etc.), U.S. (NIH, Emory university etc.), and Thailand

Observation of medical care systems to medical institutions designated for type II infectious diseases in Japan

Observation in endemic countries

Public health measures

Epidemiology / Public Health Responses:

- Discussions for contact tracing survey methods (Contact data management surveys in South Korea)
- Model development of contact tracing survey tools

Medical systems:

- Proposals to divide functions of medical institutions designated for type II infectious diseases (Diagnosis only / Complete treatments)

Medical supports:

- Establishing a system for dispatching experts to medical institutions. Dispatching two experts from NCGM.

Development of medical care and infection prevention measures

Intensive care guidelines:

Establishment of a medical guidance of intensive care for serious cases

Treatment guidelines:

- Creating antiviral treatment guidelines for treatment for MERS
- Establishing a multicenter prospective observational study system to collect epidemiological information on MERS patients
- Establishing a treatment system using recovery plasma

Infection prevention measures:

- Providing infection control videos and home handbooks for healthcare professionals and the general public
- Creating guidelines for infection prevention measures when emerging respiratory infections such as MERS occur

Offer information

Workshops for medical professionals, Edification by E-learning

What we need to address future issues 1/2:

- A framework that widely targets general medical institutions to deal with Emerging and Re-emerging Infectious Diseases (EIDs) at the regional level as a response to internationalization.
- A framework for cooperation that includes not only administrative departments and medical institutions but also biosecurity experts in order to establish a system for responding to EIDs in a multifaceted and coordinated manner.
- A framework for research and physician-led clinical trials on treatment of EIDs, and discussions for the use of unapproved drugs and off-label use of approved drugs in order to be able to respond quickly in emergencies.
- A system to enable smoother human exchange between medical institutions: supporting medical institutions by creating medical support teams organized by specialists in various fields and various medical professionals, including intensivists.

What we need to address future issues 2/2:

- An establishment of a system for instruction when multiple local governments are involved in emergencies.
- Allocation of finances and specialists/departments to develop tools for contact tracing surveys, plus discussions of the government side.
- A system for replenishing and supporting human resources that transcends the boundaries of local governments in contact tracing surveys.
- Deep discussions at the national level on how to collect action histories for the public health measures and how to publish them.





Medical equipment including a lamp and a control panel mounted on the wall.

White folding table mounted on the wall.

Two small rectangular vents or electrical outlets mounted on the wall above the doorway.



Medical control panel, a black television, a white shelf, and a round analog clock mounted on the wall.

A corkboard with a white paper pinned to it, located below the television.



White folding table mounted on the wall.

WC

症 例

当院における新型コロナウイルス(2019-nCoV)感染症患者 3 例の報告

国立国際医療研究センター

中村 啓二	忽那 賢志	鈴木 哲也	井手 聡	太田 雅之	守山 祐樹
中本 貴人	野本 英俊	秋山裕太郎	宮里 悠佑	脇本 優司	奥濱 絢子
神田 宏平	氏家 無限	木下 典子	山元 佳	石金 正裕	森岡慎一郎
齋藤 翔	早川佳代子	大曲 貴夫			

Key word: 2019-nCoV 感染症

平成 27 年度厚生労働科学研究費補助金
「中東呼吸器症候群（MERS）等の新興再興呼吸器感染症への臨床対応法開発ための研究」
（研究者代表者 大曲 貴夫）
分担研究報告書

MERS に対する抗ウイルス薬治療等の特異的治療に関する検討

研究分担者：

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忽那 賢志 （国立国際医療研究センター病院 国際感染症センター）

加藤 康幸 （国立国際医療研究センター病院 国際感染症センター）



DIAMOND PRINCESS

BBC NEWS JAPAN



Compassionate Use of Remdesivir for Patients with Severe Covid-19

J. Grein, N. Ohmagari, D. Shin, G. Diaz, E. Asperges, A. Castagna, T. Feldt, G. Green, M.L. Green, F.-X. Lescure, E. Nicastri, R. Oda, K. Yo, E. Quiros-Roldan, A. Studemeister, J. Redinski, S. Ahmed, J. Bennett, D. Chelliah, D. Chen, S. Chihara, S.H. Cohen, J. Cunningham, A. D'Arminio Monforte, S. Ismail, H. Kato, G. Lapadula, E. L'Her, T. Maeno, S. Majumder, M. Massari, M. Mora-Rillo, Y. Mutoh, D. Nguyen, E. Verweij, A. Zoufaly, A.O. Osinusi, A. DeZure, Y. Zhao, L. Zhong, A. Chokkalingam, E. Elboudwarej, L. Telep, L. Timbs, I. Henne, S. Sellers, H. Cao, S.K. Tan, L. Winterbourne, P. Desai, R. Mera, A. Gaggar, R.P. Myers, D.M. Brainard, R. Childs, and T. Flanigan

ORIGINAL ARTICLE

Remdesivir for the Treatment of Covid-19 — Preliminary Report

J.H. Beigel, K.M. Tomashek, L.E. Dodd, A.K. Mehta, B.S. Zingman, A.C. Kalil, E. Hohmann, H.Y. Chu, A. Luetkemeyer, S. Kline, D. Lopez de Castilla, R.W. Finberg, K. Dierberg, V. Tapson, L. Hsieh, T.F. Patterson, R. Paredes, D.A. Sweeney, W.R. Short, G. Touloumi, D.C. Lye, N. Ohmagari, M. Oh, G.M. Ruiz-Palacios, T. Benfield, G. Fätkenheuer, M.G. Kortepeter, R.L. Atmar, C.B. Creech, J. Lundgren, A.G. Babiker, S. Pett, J.D. Neaton, T.H. Burgess, T. Bonnett, M. Green, M. Makowski, A. Osinusi, S. Nayak, and H.C. Lane, for the ACTT-1 Study Group Members*

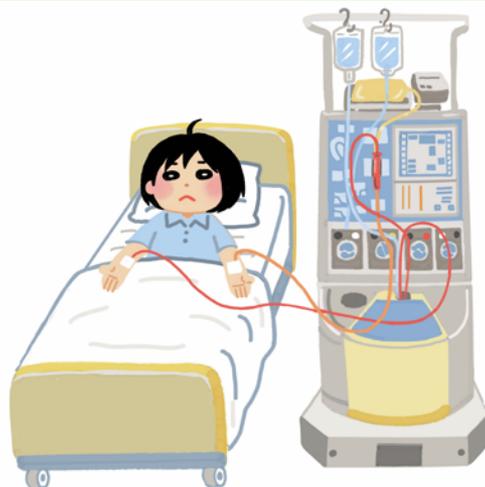
DOI: 10.1056/NEJMoa2007764

COVID-19回復者血漿を用いた治療の有効性・安全性の検討

回復者のスクリーニング



血漿の採取



血漿の投与



2020年4月末より開始
2020年10月現在、**259**名に
スクリーニングを実施

対象：新型コロナから回復し、発症から21日以上経過している方

2020年5月より開始
2020年10月現在、**89**名分の
血漿を採取・保存

対象：スクリーニング検査において、十分な抗体価があり、心機能に異常がなく、感染症スクリーニングで陰性であった方

2020年10月より開始
2020年10月13日現在、**3**名の患者に投与

対象：新型コロナと確定診断されて、入院3日以内に酸素投与を必要とする中等症の成人患者

Research and development for establishment of the treatment for COVID-19

Japan Agency for Medical Research and Development (AMED)

“Research program on development and promotion of innovative drugs for emerging and re-emerging infectious diseases”

National Center for Global Health and Medicine Hospital

Disease Control and Prevention Centre

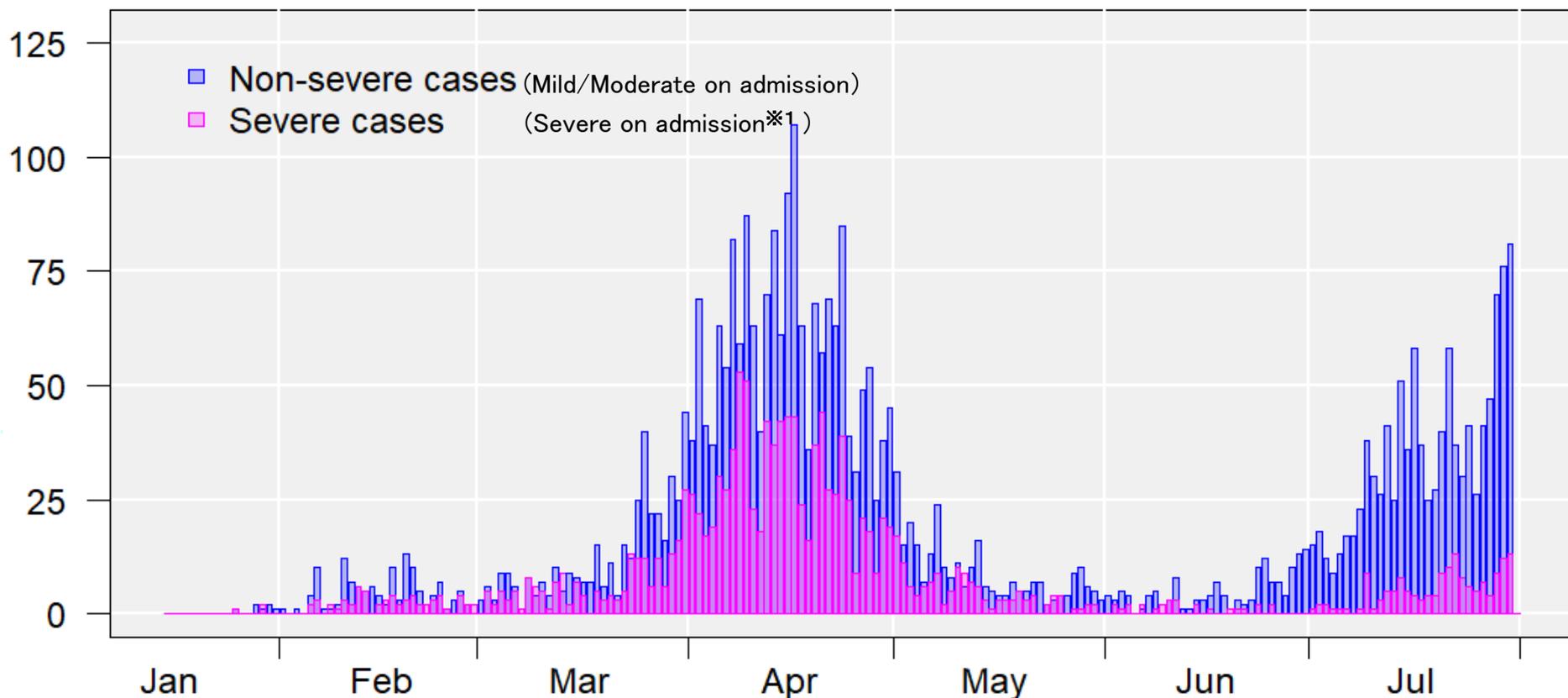
Norio Ohmagari

The logo for COVIREGI-JP features a stylized 'C' on the left, composed of a hexagonal shape formed by several triangles in shades of purple, blue, green, and yellow. To the right of this graphic, the text 'VIREGI-JP' is written in a bold, sans-serif font. 'VIREGI' is in dark blue, and '-JP' is in a lighter blue. Below this main text, the words 'COVID-19 REGISTRY JAPAN' are written in a smaller, dark blue, all-caps sans-serif font.

COVIREGI-JP
COVID-19 REGISTRY JAPAN

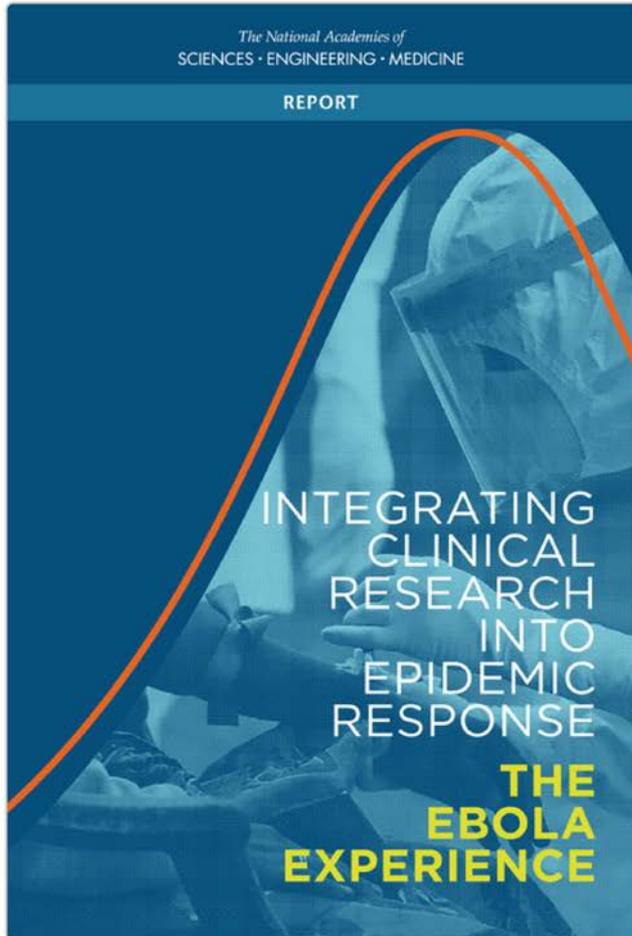
Clinical features of inpatients

- There are fewer severe cases at admission among the cases hospitalized after June than those hospitalized before June.



*1 At admission, in any case of oxygen administration, ventilator management, SpO2 94% or less, respiratory rate 24 times / minute or more

RCT is necessary in emergencies. US Opinion



Integrating Clinical Research into Epidemic Response The Ebola Experience (2017)

■ Consensus Study Report

It was once widely held that the setting of an outbreak is not an appropriate venue for conducting rigorous clinical research because when people are dying, any and all possible therapies should be “given a chance,” rather than studied in rigorous ways. Such was the case during the 2014–2016 Ebola outbreak in West Africa, when many small studies were launched and few, if any, provided conclusive results.

A thorough review of that situation by the U.S. National Academies of Sciences, Engineering, and Medicine concluded that “randomized, controlled trials are the most reliable way to identify the relative benefits and risks of investigational products, and ... every effort should be made to implement them during epidemics.”

U.S. Department of Health & Human Services
Office of the Assistant Secretary for Preparedness and Response

Preparedness Emergency About ASPR

 **Public Health Emergency**
Public Health and Medical Emergency Support for a Nation Prepared

PHE Home > About ASPR > Biomedical Advanced Research and Development Authority (BARDA)

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Biomedical Advanced Research and Development Authority

Biomedical Advanced Research and Development Authority (BARDA), part of the HHS Office of the Assistant Secretary for Preparedness and Response, was established to aid in securing our nation from chemical, biological, radiological, and nuclear (CBRN) threats, as well as from pandemic influenza (PI) and emerging infectious diseases (EID). BARDA supports the transition of medical countermeasures such as vaccines, drugs, and diagnostics from research through advanced development towards consideration for approval by the FDA and inclusion into the Strategic National Stockpile. BARDA's support includes funding, technical assistance and core services, ranging from a clinical research organization network to Centers for Innovation in Advanced Development and Manufacturing, and a fill-finish manufacturing network. BARDA supports a diverse portfolio of medical countermeasures and these products have received a total of 55 FDA approvals, licensures, or clearances.

Our mission is accomplished through successful public-private partnerships with industry to share risk, improve efficiency and accelerate development all while sustaining a marketplace that guarantees continued access to countermeasures vital to our national security. [Learn More >>](#)

Meet the Director



Gary L. Disbrow, Ph.D.
Acting Director,
Biomedical Advanced
Research and Development

Biomedical Advanced Research and Development Authority (BARDA), part of the HHS Office of the Assistant Secretary for Preparedness and Response, was established to aid in securing our nation from chemical, biological, radiological, and nuclear (CBRN) threats, as well as from pandemic influenza (PI) and emerging infectious diseases (EID). BARDA supports the transition of medical countermeasures such as vaccines, drugs, and diagnostics from research through advanced development towards consideration for approval by the FDA and inclusion into the Strategic National Stockpile.

Importance of national public-private partnerships

1. Accelerating Covid-19 Therapeutic Interventions and Vaccines

(ACTIV) in the United States

2. ACCORD (Accelerating Covid-19 Research and Development)

platform in the United Kingdom

1. Collins FS, Stoffels P. Accelerating COVID-19 therapeutic interventions and vaccines (ACTIV): an unprecedented partnership for unprecedented times. *JAMA* 2020;323:2455-2457.
2. COVID-19 treatments could be fast-tracked through new national clinical trial initiative. Press release of the U.K. Department of Health and Social Care, April 29, 2020 (<https://www.gov.uk/government/news/covid-19-treatments-could-be-fast-tracked-through-new-national-clinical-trial-initiative>. opens in new tab).
3. "Solidarity" clinical trial for COVID-19 treatments. Geneva: World Health Organization, 2020 (<https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/solidarity-clinical-trial-for-covid-19-treatments>. opens in new tab).

Challenges for the future

To prepare for emergencies that occur every few years

To carry out prompt research and development in emergencies

1. Clarification and preparation of R/D fields
2. The system that makes the above possible
 - Seeds selection
 - Allocation of finances for conducting clinical research and clinical trials
 - Establishment of research systems in clinical practices
 - Support for research fields
 - Strategic R / D by platformization