

Effect of COVID-19 on oral research in Indian scenario: An observation

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Abstract

COVID-19 pandemic is an event to remember; it has unequivocally affected every part of our lives both ways. It has opened up numerous research areas with abundant funding opportunities and avenues; oral research is just a small part of this research world. In this review, we look into oral research in the COVID-19 era and India's position in COVID-19 research. The salient features of the National Guidelines for Ethics Committee Reviewing Biomedical and Health Research during the COVID-19 pandemic have been described. Some possible research topics in dentistry during COVID-19 and the need for the impetus to the dental community for oral research have been discussed.

Keywords: COVID-19, Indian Council of Medical Research, oral research, research grants

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INTRODUCTION

COVID-19 pandemic has changed the entire world and the research scenario is also not spared by it. As the world grapples to find a cure, rapid research has emerged as the prime means to find a solution for the ongoing viral onslaught. In this current scenario, traditional hardcore research topics and their funding opportunities appear to have taken a back-seat to the front-line COVID-19 related research.

The ongoing COVID-19 research is only in its nascent phase, but it is the forerunner to tackle the challenges of this unprecedented pandemic. The World Health Organization is gathering data of the latest international multilingual scientific findings and knowledge on

COVID-19. It was built by BIREME, the Specialized Center of PAHO/AMRO and part of the Regional Office's Department of Evidence and Intelligence for Action in Health.^[1] The various research areas for COVID-19 are outlined in Figure 1.^[2]

Tuttle K felt that the COVID-19 pandemic places a tremendous strain on the clinical research setup while studies in other areas of medicine and dentistry have been affected, constrained by redirection of resources and temporary halting of in-person visits. The author also highlighted that the COVID-19 response introduced innovations that have advanced the overall conduct of clinical research by expedited preparation, ethics review and approval like never before.^[3]

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What needs to be highlighted that COVID-19 might also affect key ongoing study outcomes as the Severe acute respiratory syndrome coronavirus 2 infection tends to affect the comorbidities of patients such as glycemic

control in diabetics, raise or lower blood pressure in hypertensive patients. This may have an unprecedented effect upon the ongoing research projects encompassing patients suffering from diabetes mellitus, hypertension or any other such systemic disease. The COVID-19 enforced lockdowns also have led to changes in lifestyles, which may also affect outcomes. COVID-19 related potential confounding factors will be crucial considerations for study analysis and interpretation.

The scientific medical community has shown a renewed energy, drive and purpose to use/transform laboratory findings to solve public health issues with the help of researchers and clinicians. During this pandemic year, mutual support, collaboration and peer encouragement have helped re-examine and focus on goals for making research better.^[3]

DENTISTRY AND ORAL HEALTH RESEARCH

Dentistry can contribute significantly to the health and well-being of the community and the economy as a whole. It is not limited to large educational and academic institutions, but also small hospitals and operating clinics. However, this discipline comes with high costs of maintenance and health services. Primary research areas in dentistry are outlined in Figure 2. These are core areas that have always been in the priority for dental research and product development.

Peres *et al.*, in their The Lancet Oral Health Series, describe that dentistry discipline is never on the top priority lists of government and funding bodies, foundation, insurance agencies or policymakers. They highlight few simple reasons

- Lack of awareness of oral health importance,

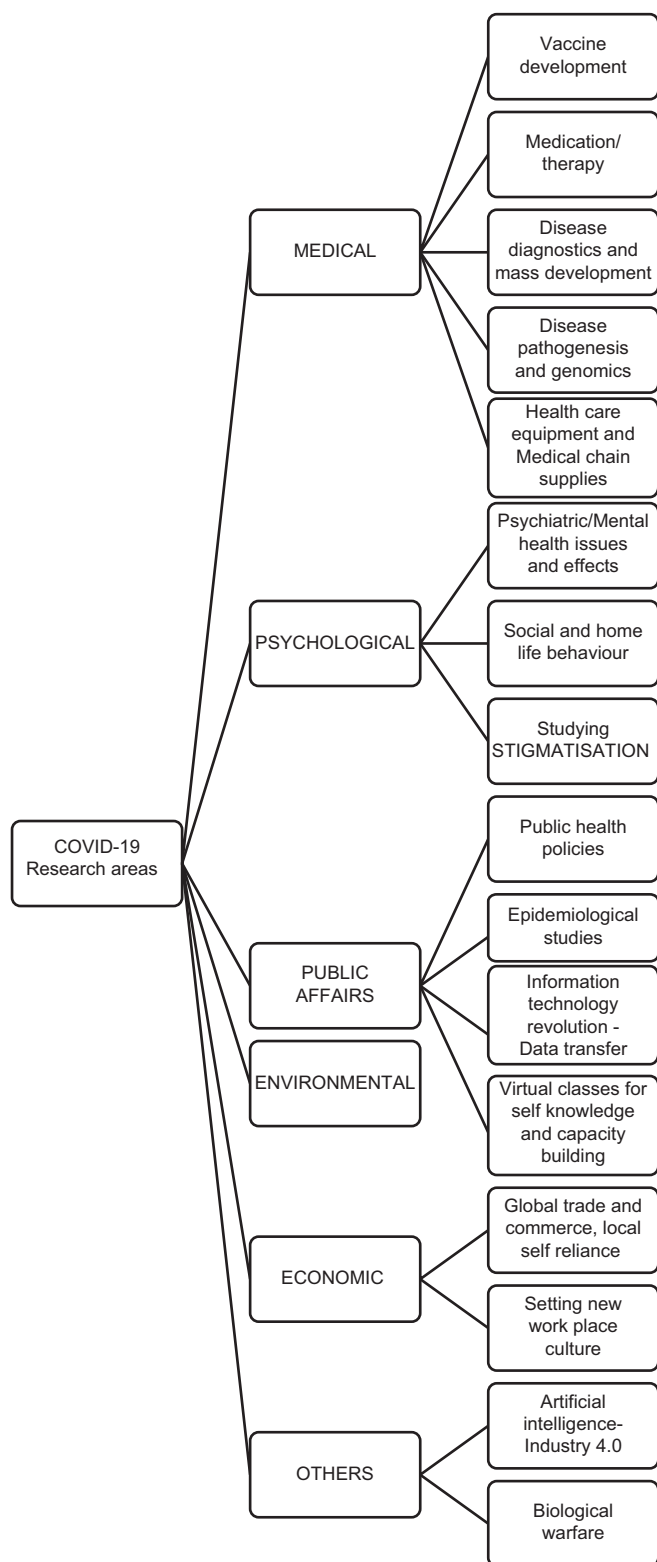


Figure 1: Proposed research areas for COVID-19. Adapted from Haleem *et al.* 2020[2]

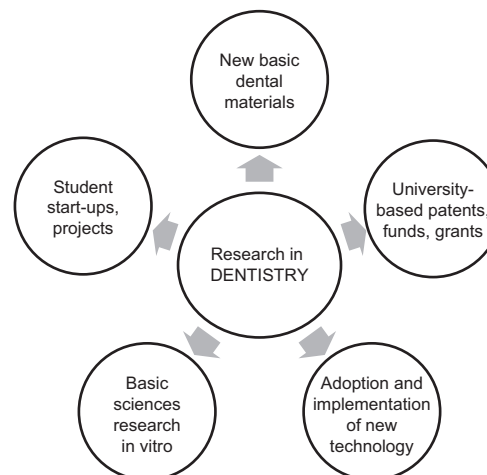


Figure 2: Priority research areas in dentistry

- Underestimation of the essential role of dentists in society welfare,^[4]
- Chronic nonlife-threatening nature of the dental disease process.

Impact of COVID-19 on dentistry

Strict government policies have been enforced regarding emergency dental and nonessential dental clinical procedures. Thus, the nonessential research activities, laboratory-based dental research projects and postgraduate student research projects have been suspended or deferred. As a result, some research focus has shifted to off-campus and electronic study means as conducting literature reviews and online surveys.^[5] A shift has occurred for utilizing the free time for personnel skill development and enhancement, attending webinars and workshops. Numerous dental education associations and regional associations have initiated numerous research projects on COVID-19 related dental issues.^[6] The rise in international and national interactions and cooperation between universities, colleges and individuals is a significant positive change. The COVID-19 outbreak resulted in the cancellation of one of the largest international dental research events in March 2020, the International Association of Dental Research conference to be held in Washington DC, USA.^[7] Similar events have been canceled worldwide – thus starting a cascade of conferences, symposiums, conventions, clinical meets getting canceled or postponed to a later date.

INDIAN PERCEPTIVE

India has the world's second highest number of COVID-19 cases^[8] but lacks in the number of COVID-19 related publications/studies or research. The data about COVID-19 research sourced from ClinicalTrials.gov show only 25 active studies from India.^[9] Research into communicable diseases has been always poor in India. In the present pandemic, medical facilities and research have received the much desired impetus.

The Indian Council of Medical Research (ICMR) leads India's fight against COVID-19. It has been actively and regularly releasing press notes, diagnostics and treatment protocols since March 2020. In April 2020, ICMR-National Centre for Disease Informatics and Research (NCDIR) released the National Guidelines for Ethics Committee Reviewing Biomedical & Health Research during the COVID-19 pandemic.^[10] A thorough understanding of these guidelines is necessary for Indian researchers wishing to collaborate or conduct COVID-19 research. An overview of the ICMR guidelines for Ethics Committee

Reviewing Biomedical & Health Research during COVID-19 pandemic is elaborated in Table 1.^[10]

The National Digital Library of India has a COVID-19 Research Resources Repository (Ideas and Funding). It lists funding options and opportunities being announced by several agencies to support COVID-19 research, related news and blogs, ideas being funded as well as trigger thoughts of researchers. The basic idea for this digital portal is to help the researcher and entrepreneurs find suitable funding options and track interesting ideas.^[11]

The University Grants Commission in September 2020 released a guidance document titled “Good Academic Research Practice” to foster an ecosystem with foremost importance to academic ethics and research integrity. This can be used as a vital reference for scholarship and science to survive in these challenging times.^[12]

Balaji summarized the future of dentistry as a result of COVID-19 disruption. Infection control and sterilization protocols, practice and research ethics, emergency protocols, teledentistry, cost-effectiveness as well as economic analysis of dental practice managements need to be revisited and realigned to suit the existing situation. All new models and ideas in dentistry also will need to be validated by research and evidence.^[13] The focus on oral and dental research in the COVID-19 era has to evolve quickly.

FUTURE DIRECTIONS

There is so much being learnt about the COVID-19 virus each day and never before such large amount of research and resources are getting invested into a relatively unknown pathogen. At the same time, the Internet has become a powerful resource for reaching millions and it shall continue to serve as an engine for social networking, education, research and collaborations.

During this period of COVID-19 isolation, there is an opportunity for dental students and practitioners to build and retain the theoretical and clinical expertise through many educational instruments. It is crucial that we encourage and support these new lines of research, raise knowledge and train our present and future workforce and faculties in this field.^[7]

The infrastructure that is being set up during this pandemic can be put into use for other purposes. Massive diversion of funds has shifted to the health-care setup. Translational work from the laboratory to the bench is now much faster. The various synergies of COVID-19 research could be used for collateral

Table 1: An overview of ICMR guidelines for Ethics Committee Reviewing Biomedical and Health Research during COVID-19 pandemic**General principles**

Four basic principles for guiding biomedical and health research: Respect for person, beneficence, nonmaleficence and justice

General ethical issues

Consider benefit-risk. Based on type of risk involved, consider the review required as exempted, expedited or full committee

Maintain privacy confidentiality of highly sensitive COVID-19 infection information

Regard distributive justice for inclusion in the research without social, racial or ethnic inequalities and conflict of interest (financial/nonfinancial) of researcher, EC members, institution and sponsors

Include payment for participation and compensation for research-related harm- financial compensation for research-related SAE through insurance, corpus funds or grants. SAE should be reported to EC within 24 h and a report on SAE relatedness (casualty) within 14 days for quantum and assistance review

Community engagement should be in a culturally sensitive manner, educate the public about pandemic (COVID-19), research, risk, etc.

Storage of COVID-19 samples with adequate safeguards with clarity on custodianship and EC approval

Collaborate for rapid data sharing while safeguarding data is critical. Foreign assistance/collaboration will need the Health Ministry's screening committee approval before initiation

Focused research on public health system preparedness and interventions to prevent, delay or contain spread

Note sociobehavioral harm in COVID-19 disaster from isolation, quarantine, segregation from families

Design alternative studies – online or remote methods. Consider that technological requirements may exclude participants without access to technology. Virtual tools for data collection must be assessed for privacy and security features by EC (case to case basis)

Identify constraints for fast track conduct of research

Agencies and sponsors need to ensure safety, care, compensation, funds and training for all engaged (at individual, societal or community level) in COVID-19 research along with preparation of public education material

Undertake expeditious review for clinical trial for new drugs and use approved MEURI

Facilitate posttrial access of successful investigational drug/vaccine free of cost to participants till same is available in the market

Responsible role of media in facilitating dissemination of useful information and not create panic

SARS-CoV-2 virus isolation and characterization should be conducted in a BSL-3 or BSL-4 laboratories as prescribed by the Department of Biotechnology and Ministry of Environment and Forests, Government of India

Telemedicine with necessary patient consent for research when possible

Ethical review procedures

Three categories of research: new research directly related to COVID-19, ongoing non-COVID research and new non-COVID research

EC must prioritize research review based on urgency and in view of social distancing norms

EC

Ensure a thorough scientific and ethical review, re-review and plan next steps for fast track review

EC to be registered with appropriate agencies

DHR - biomedical and health research

CDSCO - clinical trials as per new drug and clinical trial rules 2019

All COVID-19 related research to be registered on CTRI

EC could have a quorum of minimum of five members including medical/nonmedical or technical/nontechnical members with one nonaffiliated member

If members of local EC are unavailable, the review may be conducted by any other EC within India for initiating the study until local EC can convene its meeting

Special situations can be multiple EC, registered independent EC or institutional subcommittees that report to the main EC

Research proposals should be submitted as soft/hard copy in ICMR common forms for Ethics Review (http://ethics.ncdirindia.org/Common_forms_for_Ethics_Committee.aspx)

The EC adopts an SOP for emergency research review, plan prior review by experts and shorten timelines for accelerated procedure of electronic documents

Short agendas, frequent virtual video conference meetings for fast track review within 24–48 h

Considerations for written consent not possible in severe or isolated COVID-19 patients. Use of oral or electronic methods (via phone) to document and record consent and identify SAE

Maintaining right balance to protect privacy and disclosure of relevant information

Maintaining digital recording of meeting, online voting for decision-making by members

Common review for multicenter research in India by one main designated EC

Ensuring strict monitoring and oversight by local ECs

Continuing review and monitoring

The EC should continually evaluate progress of ongoing proposals, monitor approved study site for compliance, review SAE reports, protocol deviations/violations/noncompliance/DSMB reports/any new information/assess final reports

For protocol deviations/violations the EC should examine the corrective actions. If the violations are serious, the EC may halt the study and compensation be given

Ongoing and existing studies – Consider the impact risk of COVID-19 ongoing study recruitment and continued involvement of participants.

Consider extension, temporary halt at some/all sites; suspension/postponement of study or activation of sites that have not yet been initiated without compromising safety and well-being of patients

New non-COVID research studies treatment evaluations of chronic conditions or communicable diseases or injuries also need equal consideration. Suggestions for additional safeguards for research

Informed consent document

Challenges in obtaining consent from COVID-19 patients, hospitalized patients, children

Use of broad consent with an individual informed opt-out option may be used for research on residual clinical samples

Electronic consent*Contd...*

Table 1: Contd...

Use of technology and electronic tools of text, graphics, audio, video, podcasts, etc.
 Electronic methods (digital signature) will need EC approval priori
 Waviness of consent with adequate rationale in retrospective studies, anonymized data, public health studies, data in public domain, humanitarian emergencies when participant not in position to give consent
 Vulnerability
 Individuals/certain groups of persons who are incapable of protecting their own interests such as COVID-19 patients, socially, economically or politically disadvantaged, health-care workers in COVID-19 hospitals, terminally ill, unduly influenced or lack of autonomy
 Ensuring additional safeguards for participants and prevent stigmatization
 Ensuring safety of researcher/health-care worker is responsibility of the institution, sponsors and local authorities
 Prioritize research and schedules to prevent overcrowding
 Adequate training
 Appropriate biosafety precautions
 Expose minimum number of researchers
 Communication using electronic platforms
 Use protection gear/PPE and facilities to undertake research
 Safety against any assault from public or others
 Insurance cover
 Provide support for psychological needs and maintain good mental health and well-being of COVID-19 patients and their families

SAE: Serious adverse events, EC: Ethics committee, MEURI: Monitored emergency use of unregistered and experimental interventions, SARS-CoV-2: Severe acute respiratory syndrome coronavirus 2, BSL: Biosafety level, DHR: Department of Health Research, CDSCO: Central drug standard control organization, CTRI: Clinical trial registry of India, ICMR: Indian Council of Medical Research, SOP: Standard operating procedure, DSMB: Data and safety monitoring board, PPE: Personal protective equipment

Table 2: Hot topics for dental research in COVID-19 era

Saliva detection kits, validation of technique
 Disease transmission - aerosols
 Economical masks and respirators, validation in real-time setting
 Protocols in high-risk setting - dental operator
 Technological aspects of sterilization (UV), shields, high-volume suction, air purifiers, ventilation systems
 Teledentistry
 Dental caries vaccine

UV: Ultraviolet

development of dental caries vaccine, salivary detection kits for other medical conditions. Transmission of COVID-19 is still very speculative and dental profession is at high risk. The various hot topics for oral research in the COVID-19 era that can be explored are enumerated in Table 2.

The large Indian dental community could/should help contribute to COVID-19 research and beyond. The Indian dental community needs to seize the opportunity and work together to emerge successfully. Offering oral health-care services and stimulating the economy by organizing students, educators and workers domestically and internationally could help industry and businesses thrive. Extraordinary times need extraordinary effort!! It is our turn to get reckoned.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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