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# Unpacking the problem – country-level information gathering and priority setting for GELA



For any project the first steps involve gathering appropriate teams and finding the right information. GELA – the Global Evidence, Local Adaptation project is no exception. The project aims to maximise the impact of evidence use for children and newborns by increasing the capacity of researchers and decision makers in South Africa, Malawi and Nigeria to use global and local research and guidelines to develop locally relevant clinical practice guidelines (CPGs) for newborn and child health.

Over the last few months the first steps have included working towards the establishment of strategic Steering Groups in the three countries including representation from the national health ministries, child-health experts and non-governmental organisations. In South Africa a steering group was formed which met for the first time in August. In Nigeria and Malawi the groups are being appointed with the aim of meeting before the end of the year.

Another of the first tasks is to identify country and contextspecific priority topics – whittling down from the many topics that affect child health to priorities that can realistically be taken forward to inform healthcare guidelines at country level.

In South Africa this was aided by a scoping review undertaken to identify and assess the quality of South African CPGs for newborn and child health published between 2017 and 2022 which found that although South Africa has several recent guidelines for various topics within newborn and child health, gaps remain – both in content and reporting standards. The review recommended research to identify priority topics and address gaps.

A priority-setting process was therefore undertaken initially with Steering Group members to narrow down a list from 65 topics to a more manageable 14. Representatives from the National Department of Health (NDoH) were consulted to take cognisance of topics covered by other NDoH projects.

The resulting scaled-down list of high-level topics includes accidents and injuries, obesity, the management of long-term health conditions and anxiety, depression and post-traumatic stress disorder in children. The detailed topic list is now being surveyed among a broader group of national stakeholders.

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# More about GELA

Global health initiatives, particularly immunisation programmes, have led to reductions in under-five mortality in the last 30 years, however, low- to middle-income countries remain disproportionately affected carrying the burden of the majority of the five million deaths that occurred in children under five in 2020.

Newborn and child mortality is often due to preventable conditions, which could be managed through evidencebased CPGs – essential policy and practice tools supporting effective, safe and cost-effective healthcare. However, poor reporting standards and methodological limitations undermine their impact.

The GELA Project was established to tackle these challenges. With funding from the European and Developing Countries Clinical Trials Partnership, it's a partnership coordinated by Cochrane SA, including the Norwegian Institute of Public Health, the Norwegian University of Science and Technology, Western Norway University of Applied Science, Stellenbosch University, Cochrane Nigeria at the University of Calabar Teaching Hospital, Kamuzu University of Health Sciences, Malawi, Cochrane and the Stiftelsen MAGIC Evidence Ecosystem, Norway. (GELA is part of the EDCTP2 programme supported by the European Union – grant number RIA2020S-3303-GELA).









#### Cochrane SA Newsletter

# Point-of-care tests for detecting HIV viral molecules in infants and children aged 18 months or less

# Why is improving the diagnosis of HIV infection important?

It's estimated that 1.5 million infants are still exposed to HIV every year. If left untreated, about 50% to 60% of HIVinfected infants will die by the age of two years. Children infected before birth are especially at high risk of death. HIV is incurable; however, there are medications that suppress HIV, known as antiretroviral drugs (ART). When HIV is detected early, severe illness and death from HIV-related infections can be prevented by taking this medication. A test that detects HIV viral genetic molecules quickly and accurately at or near the patient's side (point-of-care) therefore can increase access to early appropriate treatment and minimise missing treatments in those whose HIV remains undetected.

The review aimed to determine the accuracy of molecular point-of-care tests for detecting the main types of HIV infection (HIV-1/HIV-2) in infants and children aged 18 months or less. Published reports of molecular point-of-care tests with results measured against laboratory viral-based tests (benchmark) were studied.

Twelve studies which completed 15 evaluations involving 15 120 participants compared molecular point-of-care tests for diagnosing HIV infection.

#### What are the strengths and limitations?

The review included sufficient studies and participants. All studies were conducted in sub-Saharan Africa, making the results highly applicable for use in communities where the disease is regularly found and where disease-control programmes are often targeted. However, one in three included evaluations of the molecular point-of-care tests conducted in a laboratory setting and not near the patient, however, there was no difference in the test accuracy between settings.

#### What are the implications of this review?

In theory, for a population of 1000 children aged 18 months or less where 100 have HIV infection, 100 children will be positive with the molecular point-of-care test, of which one will not have the infection (false-positive result), and 900 will be negative with the molecular point-of-care test, of which one will indeed have the infection (false-negative result).

Point-of-care nucleic acid-based testing (POC NAT) has a high sensitivity and specificity to detect or exclude HIV-1/HIV-2 infection in infants and children  $\leq$  18 months compared to laboratory-based viral assays. There was also no difference in estimates of sensitivity and specificity in evaluations of the POC NAT tests conducted in the field compared to the POC NAT evaluations in the laboratory. These tests could therefore complement or replace laboratory-based viral assays.

Larger, prospective studies are needed to evaluate the diagnostic accuracy of POC NAT in the field at point of care. Inclusion of some laboratory evaluations of the POC NAT test in this review contributed indirect evidence, which raised some applicability concerns.

The reviewers also recommend more studies evaluating the accuracy of POC NAT in the youngest ages (six weeks and earlier). More studies evaluating the impact of POC NAT tests compared to standard of care (laboratory tests) using randomised trials in real-life settings or other study designs for test impact evaluations will be important to assess the real benefit of replacing laboratory-based viral assays (Schumacher 2016). Future studies should aim to address the questions of whether time to diagnosis, time to treatment, morbidity, and mortality are reduced by POC NAT tests and further emphasise the question of the risk of a POC test versus a laboratory-based viral assay.

The evidence is current to 2 February 2021.

Citation: Ochodo EA, Guleid F, Deeks JJ, Mallett S. Point-of-care tests detecting HIV nucleic acids for diagnosis of HIV-1 or HIV-2 infection in infants and children aged 18 months or less. Cochrane Database of Systematic Reviews 2021, Issue 8. https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD013207.pub2/full

#### This review won the Cochrane Kenneth Warren Prize 2022 for Eleanor Ochodo.

It is associated with the Research, Evidence and Development Initiative (READ-It) project. READ-It (project number 300342-104) is funded by UK aid from the UK government; however, the views expressed do not necessarily reflect the UK government's official policies.



# An advocate for research transparency



**Duduzile Ndwandwe** 

"The highlight for me is the recognition of the importance of what this database holds for the country. It's a South Africa treasure. The South African National Clinical Trial Registry (SANCTR) project attracted me in the first place. I saw its redevelopment into the database that exists now," said Duduzile Ndwandwe, Cochrane SA Deputy Director, specialist scientist and project leader of the clinical trial registry portfolio which includes SANCTR and the Pan African Clinical Trial Registry (PACTR). "From a global perspective it's about understanding the importance of clinical trials - why we need them, I only really learnt that here. For me previously SANCTR was just a tick box, an administrative task – you get your number and start your trial. Now I understand that it's all about research transparency which is now even more in the forefront. The quality of the data has an impact on how that work contributes to policy or to a systematic review that ends up as policy."

"I'm advocating for the use of the registries because there is a narrative that it's just a database, that we just capture data and there's no value. In South Africa we recruit differently for clinical trials compared to the Global North. Here community teams are part of the study – and often they don't even know that the registries exist which is sad because it's valuable information they can use to foster confidence in the conduct of clinical trials. That's something I've started engaging with – giving talks to community advocacy groups."

Ndwandwe has been with Cochrane SA for five years. She previously worked with the University of the Witwatersrand's Reproductive Health and HIV Institute and the South African Medical Research Council's HIV Prevention Research Unit. She completed a Bachelors and Honours in Science majoring in microbiology and physiology. Her Masters was in Bacterial Genetics and her PhD in Molecular Mycobacteriology. She also completed a second Masters in Vaccinology from the University of Lausanne through South African Medical Research Council and Research Capacity Development funding support. She has recently been appointed Deputy Director at Cochrane SA with responsibility for the vaccine implementation research portfolio. "I originally wanted to be a medical doctor or a pharmacist," she explained. "I went into science by default. Back then we were not exposed to other career options – you became a doctor, a pharmacist, dentist or social worker. I'm shy so I thought in the lab I could play with bacterial cultures and not be disturbed by people."

So how did a shy basic scientist move into clinical trials involving people?

"My first job was at HIV Prevention Research Unit (HPRU) with Prof. Gita Ramjee. She took a chance taking a basic scientist and throwing me into clinical trial implementation which I had no knowledge of. HPRU was a fertile ground to understand how to run clinical trials. I was thrown in the deep end – I was the Clinical Research Leader for the Isipingo CRS managing the entire clinic with its staff and doing Quality Controls (QC) – I had never done all that."

At Wits RHI she worked on clinical trials testing the use of PrEP for adolescents where she learnt more about managing trials but also about community engagement. "The engagement with participants was the most exciting. Research is about being human and giving support – the clinical trial space had to be a place of comfort, a youthfriendly environment with no judgement. It was often hard."

"But it made me face my demons and forced me to deal with people."

And the transition to Cochrane?

"We were looking to relocate to Cape Town as a family," she explained. "A Cochrane ad caught my eye because I was interested in understanding the full clinical research pathway. I had used SANCTR before as a researcher and thought it would be exciting to be on the management side of a clinical trials database. So I applied."

"But I didn't initially really know the work of Cochrane," she added. "I quickly realised that Cochrane completed the puzzle, which is to understand the full process of research, all the way from basic science to systematic reviews to influence policy and practice."

#### **Prioritising vaccines**

Her other focus is on vaccine implementation research. Her International Masters in Vaccinology which she described as "the craziest time of my life" covered all aspects of vaccinology from the bench to the patient to prepare for her current work which mainly looks at improving vaccination uptake in the country and continent.

She highlighted some of the work including a project on fractional dosing for polio vaccines – to understand whether

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Practicing mindfulness on an iconic Cape Town mountain – Duduzile Ndwandwe.

it is as effective as a single shot – which it is. This work started when there was a shortage of polio vaccines and fractional dosing was an option to ensure that children receive protection against this infectious disease. Another project conducted at healthcare facilities in the Western Cape has shown a high prevalence of missed opportunities for vaccination. Interviews with parents and caregivers found that staffing and waiting times in the clinic are a problem, as well as the fact that many parents have no knowledge of the immunisation programme.

"It's worrying because what about parts of the country that are not as well resourced? The next step is to ask what we do with the data. You can't just collect data and sit quietly. We have to look at building capacity within communities and working with the facilities to reduce missed opportunities."

### **Continental and global research priorities**

Ndwandwe has also recently joined the liaison group for the Global Research Collaboration for Infectious Disease Preparedness (GLOPID-R) of which Cochrane Senior Director Charles Shey Wiysonge is co-chair of the board. She is working with Wiysonge to establish a GLOPID-R Africa hub. GloPID-R is a global alliance of research-funding organisations facilitating coordinated research related to new and emerging infectious diseases with epidemic and pandemic potential. One of its core objectives is to Identify gaps 'to align funding with research needs, especially in LMICs' including Africa. The secretariat will map the infectious disease research-funding landscape, and survey funders to increase regional engagement and membership.

"We have to develop appropriate criteria for our context and understand the research priorities that will address the "The aim is to launch the hub with a conference in 2023 to bring African funders together to co-create the continent's research priorities and develop a shared agenda for identifying, supporting and undertaking contextually relevant research."

needs of the continent. COVID has shown the need for more co-ordinated mechanisms for funding and conducting research. We need to learn the lessons for the next pandemic. The aim is to launch the hub with a conference in 2023 to bring African funders together to co-create the continent's research priorities and develop a shared agenda for identifying, supporting and undertaking contextually relevant research."

And with all of this how does Ndwandwe find family and metime?

"I do de-stress," she said. "I love hiking and I've been running some half marathons. Practicing mindfulness is hard when you are busy but when you are on a mountain you practice it. It helps in dealing with the stresses and challenges of work. You need to strike a work/life balance."

"Spending quality time with family is also a priority. I learnt a lot about my children during lockdown. When you are constantly busy you don't pay enough attention to them. I'm learning to prioritise family time."

"It's challenging," she added. "There is too much work but I look forward to going to work every day, to learning more."

"I believe in the process. I don't like setting goals as I believe the universe and the higher powers will draw you to where you are supposed to be. You have to trust the process."

## "...I believe the universe and the higher powers will draw you to where you are supposed to be. You have to trust the process."

GloPID-R is a global alliance of research-funding organisations facilitating co-ordinated research related to new and emerging infectious diseases with epidemic and pandemic potential. During the COVID-19 pandemic, GloPID-R in conjunction with another collaborative research funding group (the UK Collaborative on Development Research) facilitated cohesive COVID-19 research and supported the development of locally identified research priorities. One of its core objectives is to identify gaps to align funding with research needs, especially in LMICs. The GloPID-R collaboration seeks to establish the Africa regional hub secretariat, with the main aim of expanding its strategic focus on research preparedness and response on the African continent. See: https://www.glopid-r.org

# A review of the SANCTR and PACTR databases 2012-2022

Clinical trials are considered the backbone of biomedical research generating robust evidence on the safety and effectiveness of treatment and preventative interventions for use in routine clinical care. A clinical trial register is a database in which key administrative and scientific information about planned, ongoing and completed clinical trials is stored. A publicly accessible database of all clinical trials taking place in the African continent is essential to increase clinical trial transparency which helps to build trust in research findings. Two clinical trial registries, the Pan African Clinical Trial Registry (PACTR, https://pactr.samrc.ac.za/) and the South African Clinical Trial Register (SANCTR, https://sanctr.samrc.ac.za/) are currently hosted by Cochrane SA at the South African Medical Research Council.

## **Clinical trial activity**

In the last decade, PACTR and SANCTR have grown substantially with a total of 3485 and 2263 records registered, respectively. Most trials registered in SANCTR are Phase 3 (n = 969) while the majority (n=2619) of trials registered in PACTR do not list the phase and only 293 trials are in Phase 3 (Table 1). The majority of trials registered in SANCTR are recruiting in multiple sites from multiple countries and in PACTR the majority are recruiting in single sites. When identifying recruitment status, 1087 of the trials registered in SANCTR had a "not yet recruiting status", followed by 510 trials "completed" and 468 "still recruiting". For PACTR 1183 trials had the status "completed", while 913 are "not yet recruiting".

Table 1: Characteristics of trials registered between 2012 and2022		
Phase of trial	SANCTR	PACTR
Phase 1	362	156
Phase 2	434	191
Phase 3	969	293
Phase 4	138	226
Not Applicable*	360	2619
Recruitment sites		
Multiple sites multiple nation	1064	140
Multiple sites single nation	608	640
Single sites	591	2705
Recruiting status		
Active, not recruiting	29	151
Closed to recruitment	64	255
Completed	510	1183
Recruiting	468	885
Not yet recruiting	1087	913
Stopped early/terminated/suspended	99	88
Withdrawn	6	10
Total	2263	3484

\*Phase of trial: not applicable – includes trials that are exploring other interventions such as behavioural, educational, physical activity, etc.

The number of registered trials in SANCTR declined slightly from 2019 to 2020 due to the transition period as the database was taken over by Cochrane SA, however, registrations began to pick up from 2021 with approximately 300 trials registered after the redevelopment and launch of the new SANCTR system in August 2020.

PACTR has shown steady growth in the number of records registered each year, with a record high of 603 trials registered in 2020 and a slight decrease in 2021 and 2022. Figure 1 shows the number of trials registered in both registries by year from 2012 to 2022. The figure also shows the number of COVID-19 trials registered from 2020 to 2022. SANCTR has registered a total of 114 COVID-19 trials of which 59 were registered in 2021, while PACTR has registered a total of 95 trials – the majority of which, 38 and 37, were registered in 2020 and 2022 respectively.



Figure 1: Clinical trial registry growth 2012 – 2022

The most studied diseases as depicted in Figure 2 are infections and infestations for both SANCTR and PACTR with 1027 and 621 trials registered respectively. Other trials registered in PACTR include topics on muscles and connective tissue disease, pregnancy, childbirth, and paediatric conditions and obstetrics and gynaecological conditions. In SANCTR other diseases studied include cancer, respiratory disease and nutrition, metabolic and endocrine conditions.

"The trials registered in our clinical registries are studying diseases and conditions that affect the African continent indicating that investments in clinical research are addressing Africa's health challenges."



Figure 2: Trials by diseases 2012 – 2022

Most of the trials registered focused on treatment, followed by prevention then diagnosis/screening for SANCTR, and supportive/rehabilitation interventions for PACTR (Figure 3). Education and physical activity/nutrition interventions also featured quite substantially on PACTR.



Figure 3: Types of trials registered 2012 - 2022

## Conclusions

Clinical trial registration has improved over the years with a significant increase during the COVID-19 pandemic. The trials registered in our clinical registries are studying diseases and conditions that affect the African continent indicating that investments in clinical research are addressing Africa's health challenges. The trials registered in both databases have a strong focus on treatment and prevention. The growth in the trials registered is a positive reflection of the growing research capabilities in Africa.

## Lindi Mathebula

Cochrane SA



Lindi Mathebula at the 16<sup>th</sup> Vaccine Congress, Riva del Garda, Italy, 12 – 14 September 2022 where she gave an oral presentation titled 'A cross-sectional analysis of COVID-19 vaccine clinical trials in Africa'. "A publicly accessible database of all clinical trials taking place in the African continent is essential to increase clinical trial transparency which helps to build trust in research findings."

# On the move – news snippets from Cochrane SA staff

As always it's been a busy time at Cochrane SA enhanced by the re-opening of an 'in-person' world. Here are just a few of our recent news and travel stories



Solange Durão and Joy Oliver attended the 5<sup>th</sup> annual Collaboration for Evidence Based Public Health and Healthcare (CEBHA+) Networking Meeting in Addis Ababa, from 6 to 9 September 2022 – and the first inperson meeting since the

pandemic. The objectives of the meeting included reviewing and celebrating project achievements; discussing challenges and lessons learnt; outlining future plans, showcasing the work of CEBHA+ funded students as well as networking and capacity building. The CEBHA+ project aims to build long-term capacity and infrastructure for evidence-based healthcare and public health in sub-Saharan Africa. It is funded by the German Federal Ministry of Education and Research. See https://www.cebha-plus.org/

Tamara Kredo attended the 16<sup>th</sup> Guidelines International Network (G-I-N) Conference in Toronto, Canada from 21 to 24 September. The conference addressed the important issue of 'Making Health Choices Transparent, Equitable and Efficient'. Kredo highlighted experiences of navigating living guideline development in South Africa during the COVID-19 pandemic and was part of several workshops and presentations about the CIHR funded eCOVID-19 living map of recommendations (https://covid19.recmap.org/).

## Getting TB back on track



The 7<sup>th</sup> South African TB conference was held from 13 to 16 September in Durban, South Africa. The meeting aimed at addressing a critical juncture in TB control as a result of the COVID-19 epidemic – after declines in global TB mortality over decades an increase in TB deaths was shown in 2020.

Cochrane SA Director Charles Shey Wiysonge gave a plenary address on the topic 'Vaccine Hesitancy: What to do when we have a TB vaccine?'.

## Public-engagement workshop





Cochrane SA held a public-engagement workshop on 21 September for staff of the South African Medical Research Council led by Tasha Koch of Eh!woza. The workshop focused on the challenges of fostering public engagement highlighting practical experiences and case studies. For more about Eh!woza see the December 2021 issue of this newsletter at: https://southafrica.cochrane.org/resources/ cochrane-sa-newsletters/cochrane-sa-newsletters-2021

#### **TikToking at PHASA**



A number of Cochrane SA staff attended and presented at the Public Health Association of South Africa PHASA 2022 conference. Ntombifuthi Blose and Trudy Leong took the conference experience little further by entering a TikTok competition open to conference attendees and students. Their video titled 'COVID-19 Mythbusters' was about raising awareness and "debunking the misinformation related to COVID-19 vaccines and treatment" and earned them third prize - not bad

for their first attempt at using TikTok! Watch the video at: <code>https://t.co/YUnV3LDozE</code>



Ameer Hohlfeld attended the 6<sup>th</sup> International Clinical Trials Methodology (ICTM) Conference in Harrogate in the UK where he presented his doctoral research findings on the extent of randomised-controlled trials publication bias in sub-Saharan Africa, and ways to mitigate publication bias.



In August Cochrane SA staff gathered at Devon Valley in Stellenbosch to review Cochrane SA's Strategic Plan goals and objectives and to find some dedicated writing time.

# Introducing ..... new faces at Cochrane SA



Trudy Leong is а qualified clinical pharmacist and a clinical epidemiologist. Her experience in the South African public healthcare system made her realise the relevance of a multidisciplinary team approach to healthcare, not only locally but also collaborating internationally (adapting global evidence for local context and implementation). She believes that social accountability requires publichealth specialists to contribute to an equitable and universal healthcare system. Over the last decade, she has

been involved in the National Department of Health Essential Drugs Programme of South Africa (based on the World Health Organization Essential Medicines List model concept), focusing on the selection of essential medicines. She has co-ordinated the Primary Healthcare Standard Treatment Guidelines and Essential Medicines List (2014, 2018 and 2020 editions), as well as the Adult Hospital Level STGs and EML (2015 and 2019 editions), co-ordinated and also contributed to over 100 evidence reviews and over 20 costing analyses. Trudy has also co-authored 12 articles related to medicine access, published in peerreviewed journals. She has recently moved on to Cochrane SA to work on the GELA Project, continuing to support healthcare research for the South African context.



Sumayyah Ebrahim holds an MBChB and MMed (Surgery) from the University of KwaZulu-Natal as well as an MSc Epidemiology from Columbia University. She is a fellow of the College of Surgeons of South Africa. She is currently a lecturer at the University of KwaZulu-Natal's School of Clinical Medicine involved in the teaching of undergraduate students in General Surgery and supervising postgraduate students completing their Master of Medicine (MMED)

degrees. She also works as a senior scientist for Cochrane SA. Her research interests include HIV/TB, health-systems strengthening, health informatics and medical education.

# Cochrane SA Systematic Review Webinars 2022

22 February – Child immunization – Sara Cooper Cochrane South Africa, South African Medical Research Council

15 March – Living guideline recommendations – Elie Akl American University of Beirut, Lebanon

19 April – Introduction to meta analysis – Yusentha Balakrishna South African Medical Research Council

17 May – Introducing the eMERGe meta-ethnography reporting guidance – Emma France University of Stirling, United Kingdom

21 June – Strengthening clinical trials reporting: clinical trial registration – Duduzile Ndwandwe Cochrane South Africa, South African Medical Research Council

19 July – e-COVID recommendations map – Holger Schünemann, Tamara Lotfi McMaster University Canada

McMaster University, Canada

16 August – Sampling primary studies for inclusion in a qualitative evidence synthesis – Heather Ames Norwegian Institute of Public Health, Norway

20 September – Evidence informed decision-making – Taryn Young Stellenbosch University, Centre for Evidence-Based Health Care

18 October – How to communicate findings from systematic reviews: writing informative statements (GRADE guidance 26) – Nancy Santesso Cochrane Canada, McMaster University

# Conferences

6<sup>th</sup> Global Public Health Conference (GLOBEHEAL 2023) 23 - 24 February 2023

Colombo, Sri Lanka Theme: Building Bridges for Future Public Health Preparedness and Response https://healthconference.co/

11<sup>th</sup> SA AIDS Conference 2023

2023 20 - 23 June 2023 Durban, South Africa Theme: Act, Connect and End the Epidemic https://www.samrc.ac.za/

calendar/11th-sa-aidsconference-2023-20-23-june-2023-durban

12<sup>th</sup> IAS Conference on HIV Science 23 to 26 July 2023 Brisbane, Australia and virtually https://www.iasociety.org/ conferences/IAS2023

**2023 Cochrane Colloquium** 4 – 6 September 2023 London Theme: Forward together for trusted evidence https://colloquium2023. cochrane.org/

Evidence 2023 – Africa Evidence Network 13 – 15 September Entebbe, Uganda https://www. africaevidencenetwork.org/en/

18<sup>th</sup> GIN Conference 2023 19 – 22 September Glasgow, Scotland https://g-i-n.net/save-the-dategin-2023-is-coming-to-glasgow

Global Alcohol Policy Conference 24 – 26 October 2023 Cape Town Theme: Investing in people before profits https://gapc2023.samrc.ac.za/

International Conference on Evidence-Based Healthcare 11 – 12 November 2023 Tokyo, Japan https://waset.org/evidencebased-healthcare-conferencein-november-2023-in-tokyo



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