Workshop Report Title

BUILDING THE NATIONAL EVALUATION SYSTEM FOR MEDICAL DEVICES: USING REAL WORLD EVIDENCE TO IMPORVE DEVICE SAFETY AND EFFECTIVENESS

"Harnessing the digital revolution for medical device evaluation"

Workshop leads: Dr. Fadia Tohme-Shaya, University of Maryland Baltimore and Dr. Gregory Pappas, FDA, CDRH

University of Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI)

Food and Drug Administration

Co-Sponsored by FDA and University of Maryland Center for Excellence in Regulatory Science (CERSI)

Building the National Evaluation System for Medical Devices: Using Real-World Evidence to Improve Device Safety and Effectiveness
"Harnessing the Digital Revolution for Medical Device Evaluation"

Thursday, March 24, 2016
University of Maryland School of Pharmacy, 20 N. Pine Street, Baltimore, MD

AGENDA

Time	Activity
7:30-8:30 am	**Registration**
8:30-8:35 am	**Welcome** *Natalie D. Eddington, PhD, FAAPS, FCP* *Dean and Professor, Executive Director of University Regional Partnerships* *University of Maryland School of Pharmacy*
8:35-8:40 am	**Introductions** *Fadia Tohme-Shaya, MPH, PhD* *Professor & Vice Chair for Academic Affairs* *Pharmaceutical Health Services Research* *Associate Director, Center on Drugs and Public Policy* *University of Maryland School of Pharmacy*
8:40-9:00 am	**Keynote** **FDA Perspective on a National Medical Device Evaluation System** *Jeff Shuren, MD, JD* *Director, Center for Devices and Radiological Health (CDRH), FDA*
9:00-10:00 am	**Session 1: Harnessing the Digital Revolution for Medical Device Evaluation** **Moderator:** *Gregory Pappas, MD, PhD* *Associate Director, National Device Evaluation, CDRH, FDA* **Building the National Evaluation System for Medical Devices (NESMD): Work of the Planning Board** *Gregory Daniel, PhD* *Deputy Director, Duke-Margolis Center for Health Policy, Duke University* **Tools and Methods for Building the NESMD in a New Era – The Role of MDEpiNet** *Matthew Brennan, MD, MPH* *Co-Director, STS Analytical Center, Duke Clinical Research Institute (DCRI), Duke University*

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AGENDA

Time   **Activity**

Unique Device Identification: Building Block for the National Evaluation System
Terrie Reed, MS Industrial Engineering
Senior Advisor for UDI Adoption, Office of Surveillance and Biometrics, CDRH, FDA

Questions

10:00-10:15 am   **Break**

10:15-12:00 pm   **Session 2: Foundations for the National Evaluation System: Where Are We Today?**
Moderator: *Francis B. Palumbo, PhD, Esq.*
                Professor &Executive Director, Center on Drugs & Public Policy,
                University of Maryland School of Pharmacy

- **Building Coordinated Registry Networks : A Core Strategy to Build the National System**
  Art Sedrakyan, MD, PhD
  Professor of Healthcare Policy and Research in Cardiothoracic Surgery,
  Weill Cornell Medical College

  Discussant:
  The Case for Orthopedics
  Andrew N. Pollak, M.D.
  Chair, Department of Orthopaedics, University of Maryland School of Medicine

- **Big Data Analytics: Statistical Tools for the NESMD**
  Nelson Lu, PhD
  Mathematical Statistician, Office of Surveillance and Biometrics, Division of Biostatistics, CDRH, FDA

  Discussant:
  Analyzing Device Risk Using Textual Databases
  Monifa Vaughn-Cooke, PhD
  Assistant Professor, Department of Mechanical Engineering,
  University of Maryland

- **Using Real-World Evidence for Regulatory Decisions & Practice**
  Danica Marinac-Dabic, MD, PhD
  Director, Division of Epidemiology, CDRH, FDA

  Discussant:
  The Case for Interventional Cardiology Devices
  Anuj Gupta, MD, F.A.C.C., F.S.C.A.I.
  Director of The Cath Lab, Department of Medicine,
  University of Maryland School of Medicine

AGENDA

Time	Activity
12:00-1:00 pm	**Lunch**
12:00 – 4:15 pm	**Scientific Information Tables**

- **Epidemiology Regulatory Science Program/ MDEpiNet Public Private Partnership, CDRH, FDA**
  Benjamin Eloff, PhD, Marta Steliac, MS, and Danica Marinac-Dabic, MD, PhD
  Division of Epidemiology, CDRH, FDA

- **Unique Device Identifier (UDI)/MedSun, CDRH, FDA**
  Linda Sigg, Associate Director for Informatics
  Terrie Reed, MS Industrial Engineer, Senior Advisor for UDI Adoption and
  Jill Marion, MS, MBA, PMP, Director, Medical Product Safety Network (MedSun),
  CDRH, FDA

- **National Library of Medicine (NLM)**
  Steve Emrick, Head, Terminology Quality and User Services
  Patrick McLaughlin, RxNorm, DailyMed and AccessGUDID Support Lead
  Josh Temple, AccessGUDID Applications Developer,NLM, National Institutes of
  Health (NIH)

- **PCORnet**
  W. Shuyler Jones, MD
  Assistant Professor, Department of Medicine, Duke University School of Medicine

- **University of Maryland School of Pharmacy**
  Colleen Day
  Graduate Program Coordinator, Pharmaceutical Health Services Research,
  University of Maryland School of Pharmacy

- **NIH Health Care Systems Research Collaboratory Program**
  Wendy Weber, ND, PhD, MPH
  Chief, Clinical Research in Complementary and Integrative Health Branch, Division
  of Extramural Research, NIH

AGENDA

Time | **Activity**

1:00-3:00 pm

Session 3: Nodes in the Network: Making the Learning Health Care System Real
Moderator: *Fadia Tohme-Shaya, MPH, PhD*
Professor & Vice Chair for Academic Affairs, Pharmaceutical Health Services Research, University of Maryland School of Pharmacy

Presentations:

- **Sentinel**
  Nandini Selvam, PhD
  Senior Director, Government & Academic Research, Healthcore

- **PCORnet**
  W. Shuyler Jones, MD
  Assistant Professor, Department of Medicine, Duke University School of Medicine

- **MDEpiNet**
  Danica Marinac-Dabic, MD, PhD
  Director, Division of Epidemiology, CDRH, FDA

- **NIH Health Care Systems Research Collaboratory Program**
  Laura Dember

- **Patient Stakeholder**

- **NESMD**
  Gregory Daniel, PhD
  Deputy Director, Duke-Margolis Center for Health Policy, Duke University

Panel Discussion with Session 3 Presenters: How Can Nodes in the Network Bring Together Their Real-World Evidence to Promote the Learning Health Care System and Improve Medical Device Safety and Effectiveness?

3:00-3:15 pm

Break

AGENDA

Time | **Activity**

3:15-4:15 pm | **Session 4: Parallel Discussions (Attend Session A or Session B)**

Session A 2nd Floor, Rm 201 South	Session B Main Auditorium
Panel: MDEpiNet Public Private Partnership for Building a National Evaluation System Using Real-World Evidence **Moderator:** Benjamin Eloff, PhD Division of Epidemiology, CDRH, FDA	**Roundtable:** Unique Device Identification **Roundtable Facilitators:** Linda Sigg, Associate Director for Informatics, CDRH, FDA Terrie Reed, MS Industrial Engineer Senior Advisor for UDI Adoption, CDRH, FDA Jill Marion, MS, MBA, PMP Director, Medical Product Safety Network (MedSun),CDRH, FDA Mike Schiller, Senior Director of Supply Chain, Association of the Healthcare Resource and Materials Management(AHRMM)
MDEpiNet is a Public Private Partnership (PPP) that brings together leadership, expertise, and resources to build a national medical device evaluation system by improving and integrating real-world data infrastructure, developing appropriate methodologies, and conducting relevant studies. The MDEpiNet PPP is composed of over 100 national and international organizations including FDA and world-leading academic institutions, national and international patient registries, healthcare organizations, medical device industry partners and patient and consumer groups. MDEpiNet was initially stood up in 2010 and supported by a series of FDA grants. In 2014, MDEpiNet evolved into a true PPP with a Methodology Center at Harvard University, a Science and Infrastructure Center at Weill Cornell Medical College, and a Coordinating Center at Duke University. In this session participants will learn about the components of the MDEpiNet PPP, as well as potential opportunities for getting involved.	Adoption of a structured device identification system like UDI is expected to produce significant benefits to patient care, device safety, and healthcare efficiencies. Since realizing the value of UDI will require changes to healthcare technology infrastructure and process, successful adoption necessitates a commitment to share knowledge and develop best practices across all stakeholder groups affected by the inclusion of UDI in health information. This session will be used to provide more details about this game changing identification system and allow participants to share information about their own UDI planning and adoption efforts. Participants will be invited to share their perspectives on a new Learning UDI Community (LUC) that is being created to support stakeholders from academia, healthcare, government, medical device industry, and patient advocacy groups who are committed to UDI adoption.

AGENDA

Time	Activity
4:15-4:30 pm	**Closing Remarks**

Wrap-up
Fadia Tohme-Shaya, MPH, PhD
Professor & Vice Chair for Academic Affairs, Pharmaceutical Health Services Research,
University of Maryland School of Pharmacy

Next Steps
Gregory Pappas, MD, PhD
Associate Director, National Device Evaluation, CDRH, FDA

Time	Activity
4:30 pm	**Adjourn**

SOP/FDA Talk Post-Market Device Regulation

March 22, 2016 | *By Karen Robinson*

Collecting and analyzing real-world evidence could help ensure the safety and efficacy of implantable medical devices once they have hit the market. However, the infrastructure necessary to gather and process this post-market data collection does not currently exist. The University of Maryland School of Pharmacy and the U.S. Food & Drug Administration (FDA) have partnered to examine this issue in-depth. A daylong conference at the School of Pharmacy on Thursday, March 24 will gather experts to consider the problem and potential solutions. The conference and the partnership are part of the Maryland Center of Excellence in Regulatory Science and Innovation ⟳ (M-CERSI), an FDA-funded collaboration between the University of Maryland, Baltimore and the University of Maryland, College Park (UMCP).

"More and more people are living with implantable devices, and at increasingly younger ages," says conference organizer **Fadia Tohme-Shaya, PhD, MPH**, professor and vice chair for academic affairs of the Department of Pharmaceutical Health Services Research at the School of Pharmacy. "We need to work toward a system that informs providers and patients in real time about what is the best device option for them at the time they need it, and provide enough data to weigh risk and benefit. These decisions are often irreversible. Unlike the arguable ease of switching medications, the decision to replace an implantable device is often very difficult if not impossible."

The issue surrounds the safety of implantable medical devices such as heart stents, pacemakers, hip and other prosthetics. The collection of data after a medical device has met regulatory approval – real-world evidence gathered once the device is in use in the marketplace – could provide valuable information to improve device safety and effectiveness. But to collect and analyze that data, a new system is necessary. This infrastructure would require strong public-private partnering and innovations in informatics, epidemiology, biostatistics, and health care data systems integration. The FDA's Center for Devices and Radiological Health ⟳ (CDRH) has laid a foundation for a new national evaluation system for medical devices, and last year two multi-stakeholder groups issued reports providing recommendations on moving the project forward.

The conference, "Building the National Evaluation System for Medical Devices: Using Real World Evidence to Improve Device Safety and Effectiveness," will bring together clinicians, researchers, and representatives from the medical device industry, professional societies, health care delivery systems, patient advocacy groups and the FDA. Presenters include Tohme-Shaya; the director of the FDA's CDRH Jeff Shuren, MD, JD ⟳; Greg Pappas, MD, PhD, associate director for national device evaluation at CDRH; representatives of the MDEpiNet, a public-private partnership devoted to ensuring the safety and efficacy of post-approval medical devices; and many more researchers from the FDA, the National Institutes of Health, PCORnet, the National Library of Medicine, and other schools and universities, including Weill Cornell Medical College, Duke University, the University of Maryland School of Medicine, and UMCP.

Media are welcome to attend. For more information or to speak with the conference organizers, please contact Karen Robinson, 410-706-0023, *karobinson@umaryland.edu*.

<u>**Keynote**</u>
FDA Perspective on a National Medical Device Evaluation System
Jeff Shuren, MD, JD
Director, Center for Devices and Radiological Health (CDRH), FDA

- Dr. Shuren provided an overview of the challenges associated with the fast-paced field of medical devices technology and CDRH's attempts to keep-up with the regulatory evaluations of these technologies. He provided an insight into the National Evluation System developed for the medical devices, the investments and achievements so far and the ket contributers
- He outlined the 2016-2017 CDRH strategic priorities which are – establish a national evaluation system for medical devices, partner with patients, and promote a culture of Quality and organizational excellence. And an increased access to the real-world evidence to support regulatory decision making is pivotal to the completion of the above priorities.

<u>**Session 1: Harnessing the Digital Revolution for Medical Device Evaluation**</u>

Moderator: Gregory Pappas, MD, PhD
Associate Director, National Device Evaluation, CDRH, FDA

Building the National Evaluation System for Medical Devices (NESMD): Work of the Planning Board
Gregory Daniel, PhD
Deputy Director, Duke-Margolis Center for Health Policy, Duke University

- NESMD is envisioned as a strategically-driven, coordinated network of voluntary partnerships working towards generating higher quality data at lower costs to inform and improve patient care. Potential demonstration projects include to – quantify potentially serious but rare adverse events in Class II devices, build an automated efficient safety surveillance system, use existing registries for re-purposing effectiveness evaluations and promote methods for patient-driven evaluations.
- The NESMD network of partners include – Sequoia Project, Private health plans, FDA, coordinated registry networks, PatientsLikeMe, integrated delivery systems, sentinel, MDEpiNet, manufacturers, CROs, CMS, PCORnet etc.

Tools and Methods for Building the NESMD in a New Era – The Role of MDEpiNet
Matthew Brennan, MD, MPH
Co-Director, STS Analytical Center, Duke Clinical Research Institute (DCRI),
Duke University

- The MDEpinet is an organization of individuals from academia, industry and government with a mission of bringing innovation to patients. It is working to build infrastructure and data partnerships, develop methodologies and support priority pilot programs.
- Their major focus is on better data build-up and minimizing error on the data collection level and then using effecitve methodologies to efficiently and effectivelly harness the full scope of the data through robust methodologies and answer the key questions about comparative and effecitveness evaluations of medical devices.

Unique Device Identification: Building Block for the National Evaluation System
Terrie Reed, MS Industrial Engineering
Senior Advisor for UDI Adoption, Office of Surveillance and Biometrics, CDRH, FDA

- UDI are device plus product identifiers for medical devices and they are important for unique tracking for safety surveillance in the post-marketing phase. Not only is the assignment of this number mandatory but this number is important to care providers, manufacturers, suply chain, researchers and mainly the NMDES.
- The UDS promises to be the link between patient and device that can improve ability to detect and respond to safety issues, introduce efficiency in recalls, reduce medical errors, and increase precision of the real-world evaluations. The speaker impresses the need for development of a community of relevant stakeholders to help adoption of the UDI system.

Session 2: Foundations for the National Evaluation System: Where Are We Today?
Moderator: *Francis B. Palumbo, PhD, Esq.*
Professor &Executive Director, Center on Drugs & Public Policy,
University of Maryland School of Pharmacy

Building Coordinated Registry Networks : A Core Strategy to Build the National System
Art Sedrakyan, MD, PhD
Professor of Healthcare Policy and Research in Cardiothoracic Surgery,
Weill Cornell Medical College

- Providing with a real-case example of a possible medical error that was avoided among a patient with prothetic heart valve, Dr. Sedrakyan impressed upon the audience the need of evidence to inform practice of medical device usage.
- In his case to provide evidence, he focused on the need to build registries and discussed the key components to be included and considered while utilizing these registries as a data source for safety and effectiveness evaluations of medical devices.

Discussant:
The Case for Orthopedics
Andrew N. Pollak, M.D.
Chair, Department of Orthopaedics, University of Maryland School of Medicine
- Presented with examples cases where the clinical need and judgement of the treating orthopedic took precedence over the evidence present or lacking. He also presented cases where the size of the end-market may present challenges in terms of economically sustaining an evaluation system.

Big Data Analytics: Statistical Tools for the NESMD
Nelson Lu, PhD
Mathematical Statistician, Office of Surveillance and Biometrics, Division of Biostatistics,
CDRH, FDA
- The speaker discussed the potential utilization of NESMD, possible biases due to confounding, and methods (analysis, design, propensity score matching) that would be useful to counter this bias. He also provided with examples to better explain these methods to the audience

Analyzing Device Risk Using Textual Databases
Monifa Vaughn-Cooke, PhD
Assistant Professor, Department of Mechanical Engineering,
University of Maryland
- The speaker discussed how textual data is collected, how the fields such as reason for recall, problem code, and component code are key for assessing risk. Further how the text parsing, filter and clustering is used to quantify this qualitative evidence and how this feeds into the current FDA requirements was covered. The presentation was concluded with recommendations for effective utilization and management of textual data.

Using Real-World Evidence for Regulatory Decisions & Practice
Danica Marinac-Dabic, MD, PhD
Director, Division of Epidemiology, CDRH, FDA
- The speaker opened the discussion with the importance of RWE to assess the safety and effectiveness of medical devices. She gave the acronym "LEVIS" to the audience which

stands for leveraged, embedded, valuable, inexpensive/innovative, and sound science. She shared a few successes of the RWE in safety assessment of cardiovascular devices, potential partnership and highlighted the need for methodologies to match-up to the growing data and yield better evidence for the future comparative assessments for medical devices.

The Case for Interventional Cardiology Devices
Anuj Gupta, MD, F.A.C.C., F.S.C.A.I.
Director of The Cath Lab, Department of Medicine,
University of Maryland School of Medicine

- The speaker provided a background and epidemiology of patients who undergo aortic stenosis. Through this case he pointed out that long-term implication of an implanted medical device is one of the major concerns for a cardiologist and for the patient. He also pointed out that there is gap in the evidence with respect to the impact of these devices by differential age and medical history. He concluded that these gaps can indeed be filled by robust research using RWE and highlighted the role of MDEpiNet.

Scientific Information Tables

National Library of Medicine (NLM)
Steve Emrick, Head, Terminology Quality and User Services
Patrick McLaughlin, RxNorm, DailyMed and AccessGUDID Support Lead
Josh Temple, AccessGUDID Applications Developer,NLM, National Institutes of Health (NIH)

- The speaker highlighted search strategies to be used and the literary vocabulary relevant to implantable devices.

NIH Health Care Systems Research Collaboratory Program
Wendy Weber, ND, PhD, MPH
Chief, Clinical Research in Complementary and Integrative Health Branch, Division of Extramural Research, NIH

- The speaker introduced the audience to NIH collaborator projects and demonstration project interventions. She also provided the case of pragmatic trial demonstration projects and the overview of the collaborator activities.

Session 3: Nodes in the Network: Making the Learning Health Care System Real
Moderator: *Fadia Tohme-Shaya, MPH, PhD*
Professor & Vice Chair for Academic Affairs, Pharmaceutical Health Services Research,
University of Maryland School of Pharmacy

<u>**Presentations**</u>

Sentinel
Nandini Selvam, PhD
Senior Director, Government & Academic Research, Healthcore
- The speaker provided an overview of the FDA Sentinel initiative, its application in the field of medical device safety and the role of Healthcore

PCORnet
W. Shuyler Jones, MD
Assistant Professor, Department of Medicine, Duke University School of Medicine
- The speaker highlighted the goal of PCORnet, and put forth the over arching objectives of the group – create infrasturcture for CER, utilize the electronic healthcare records, and engage patients and other stakeholders throughout the process. She highlighted the capabilities of PCORnet and their active role in enagaging patients in clinical trials.

Health / Picture of Health

New system in the works to better track faulty medical devices

By **Meredith Cohn · Contact Reporter**
The Baltimore Sun

MARCH 24, 2016, 8:04 PM

A rtificial hips that shed bits of metal, stents that fail to open arteries and many other medical devices have been recalled after they caused patients harm, sometimes years after they were sold to the public.

The U.S. Food and Drug Administration now says it's a priority to more quickly share information about faulty products within the medical community and with the public.

The agency is working with the University of Maryland and other institutions to develop an easily accessible system that will begin collecting and analyzing real-time data as soon as devices hit the market. The effort aims to not only help protect patients from harmful products but steer them to innovations showing unexpected or special benefits.

"There are a lot of things we don't know when a technology comes on the market," said Dr. Jeffrey Shuren, director of the FDA's Center for Devices and Radiological Health. "We get a lot of data from clinical practice... How do we better leverage real-world data?"

Dr. Shuren was among several researchers and government regulators who spoke Thursday during a symposium at the University of Maryland School of Pharmacy to outline a new evaluation system.

Much of the data on the $133 billion medical device industry already is being collected by industry, insurers, health systems and other private networks but the information isn't linked or widely available. Planning for the new public-private effort to connect it began in 2014 and officials now hope to design a system to monitor every medical device regulators approve for use.

Such a system is vitally important given that millions of people now have implanted heart, orthopedic, contraceptive and other devices, and more people are getting them while they are relatively young, said Fadia Tohme-Shaya, a Maryland professor who is helping lead the effort through the Maryland Center of Excellence in Regulatory Science and Innovation. The center is an FDA-funded collaboration between the University of Maryland campuses in Baltimore and College Park.

Doctors today are replacing joints in people in their 30s or 40s, wrecked from activity rather than age, making the durability of devices more important, especially as people live longer, she said.

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Despite arduous testing before devices gain approval, Tohme-Shaya said it remains difficult to determine what device may be best for a patient because the available information is limited. Problems and questions often aren't apparent until after hundreds or thousands of devices have been implanted.

"Most everyone knows someone living with a device like a pacemaker, a hip or a stent, and they themselves might be living with one," said Tohme-Shaya, professor and vice-chair for academic affairs and associate director of the Center on Drugs and Public Policy in the Maryland School of Pharmacy. "Unlike with drugs, it's hard to switch to a new device. When something goes wrong it's rarely an option for the patient to have it removed."

The collaborative database could help catch device defects or unintended consequences in patients earlier, allowing for tweaks or advice to doctors and limiting major recalls, she said.

The FDA has issued about a dozen top-level recalls so far this year, meaning those products could cause serious injury or death. Many more less serious recalls occur annually.

The system also could pinpoint who is benefiting the most from devices, allowing manufacturers to market more effectively or even customize products. That could tell doctors which artificial joints work best in runners, for example, or which stents are safest for certain heart patients, said Dr. Matthew Brennan, a cardiologist and co-director of the STS Analytical Center at Duke University's Clinical Research Center.

He cited a recently approved kind of stent that is made of a polymer that the body absorbs. While it could "revolutionize the market" by eliminating complications from implanting metal, it now appears to create scar tissue that can cause new blockages. And polymer stents coated in medication to prevent the scarring may lead to more dangerous blood clots

"The polymer ones are supposed to prop open an artery and then go away," Brennan said. "The question now is what is the real-world outcome. I won't have to wait four years, after millions have been placed, to see which patients benefit. There also may be a downside that didn't come to light in trials."

Others at the symposium said the biggest challenge with building a new system is getting everyone to share information, though public, industry and health groups are now at the table, FDA officials and researchers said.

Other issues will be technical, such as a separate but intertwined effort to label each device manufactured. That specific data could help quickly identify what happened to a defective batch of devices, for example, but pose other problems, such as added cost, said Dr. Andrew N. Pollak, chair of the University of Maryland School of Medicine's department of orthopedics.

The FDA already has begun requiring unique identifiers for devices.

While a national evaluation system has tremendous potential to provide doctors with important information about devices, Pollak said it will be important to insure the data isn't skewed. Some failures are not due to the

devices but because of a patient's behavior or circumstances, such as when a car crash victim's fractures become infected, he said.

A big issue for manufacturers might be "signals" given off by a device that erroneously indicates a problem, said Theodore Heise, vice president for regulatory scientific affairs at Cook Medical, a Bloomington, Ind.-based device maker. That could put off doctors, scare patients and even lead to litigation, while denying some patients a needed medical advance, he said.

Still Heise sees many positive possibilities with sharing information, including the ability to quickly add or change features to benefit more patients, and avoiding or minimizing recalls.

"Our concern," he said, "would be that a device is not completely evaluated."

The FDA's Shuren said ensuring quality data goes into the system and proper analysis would be critical to handling such signals. Pushing the data out to doctors in a timely way also would be necessary to make sure patients have information on the products, a concern of consumer advocates.

The task now, Shuren said, is to work out the details.

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