Meet NEST: Building a National Medical Device Surveillance System

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April 4, 2018
Why do we need this system?

• More efficient and timely achievement of our public health goals -- assuring safe and effective devices
• Bring life saving devices to patients more quickly
• Improve our ability to detect safety issues by moving to more active surveillance
• Expand our ability to study how devices perform in diverse populations

Learning Health Care System: a network of networks
Value created by multiple users of data

**Patients/ Clinicians**
- More timely access to safer, more effective devices
- Better information about the use of a given device in practice

**Hospitals, Health Systems**
- Improved quality
- Reliable assurances of safety
- Possibly, reduced reporting requirements

**Payers**
- Access to high-quality evidence on device performance in clinical practice

**Medical Device Industry**
- High-quality evidence at lower cost, in less time, to support premarket approval/clearance, payer coverage
- Meet or reduce the need for postmarket study and adverse event reporting requirements
- Potential for premarket-postmarket shift owing to strong assurances that postmarket RWE would be generated
- May obviate the need for FDA premarket review of some device modifications because more timely and informative routine data collection
FDA/CDRH has been **promoting RWE** since 2010, NEST coordination center created in 2016.
Success to date

- >50 regulatory decisions including label expansions, post-approval studies, and surveillance demonstrate that RWE can be “better, faster, and cheaper.”
- Increasing access and use of RWE a CDRH strategic priority
- Post approval studies of TVT, vascular, orthopedic, PAS of implantable cardioverters
- Next generation sequencing tests for cystic fibrosis
- Pre market- Expanding indication to pediatric populations for wearable defibrillators, TVT
- Registries providing control cohorts
TVT CRN Case Study: creating value

- Transcather Value Therapy devices: US was 42rd in the world to approve

ACC/STS Registry

CMS claims data

TVT CRN

TVT use to make the US is first in the world approvals.
TVT CRN Case Study: creating value

• Transcatheter Value Therapy devices: US was 42rd in the world to approve

TVT CRN

ACC/STS Registry

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TVT use to make the US is first in the world approvals.
Return on investment: case study of the TVT CRN

Estimated Cost Savings:
$108 million

Return on Investment:
\[
\frac{\text{Cost Savings}}{\text{Cost of TVT CRN Studies}} = \frac{$132 - 24.05 \text{ MM}}{$25.05 \text{ MM}} = 430\%
\]
UDI Status

• Sep 24, 2014, deadline for submission of Class III DI records to GUDID

• Jan 26, 2015 – Accepting GUDID Accounts for Implant/Life-Supporting/Life-Sustaining (I/LS/LS) devices

• September 24, 2015, deadline for submission of I/LS/LS devices records

• Total GUDID DI Records ~75,000*

*Data as of June 12, 2015
FDA has promoted the development of NEST through development of public private partnership

- NEST established by Medical Device Innovation Consortium under a cooperative agreement with FDA
- Supported through MDUFA funds

http://mdic.org/cc/about-nestcc/
NEST’s multi-stakeholder board

Working with stakeholders across the medical device ecosystem to catalyze the timely, reliable, and cost-effective development of Real-World Evidence to enhance regulatory and clinical decision-making.
National Evaluation System for health Technology (NEST) : The device ecosystem is creating a coordinating body to lead this growth

- Establish **partnerships** with a range of organizations, companies, and collaborations that provide data and analytics solutions
- Set **data quality for data partners and methods standards** for observational and randomized studies
- Designation of demonstration projects
- Establishment of data partnerships
- Offer **value** through products and services to key stakeholders in the ecosystem
MDEpiNet: NEST Data partner building CRNs

• Develop national & international strategies for infrastructure development for use of real work evidence
• Innovate methodological approaches for robust device evaluation across total product life cycle
• Work through Public Private Partnership

To improve evidence generation for medical device safety and effectiveness throughout the device life cycle

Over 130 partners including industry, health care providers, specialty societies, payers, academia, and patient organizations
MDEpiNet is building Coordinated Registry Network (CRNs) as part of NEST

Address ecosystem questions efficiently

Harmonization/Interoperability

States Data

EHR

Registry

Registry

Registry

Structured Data Capture (SDC)

Health Care Providers

Patients

Government

Device Industry

EHR Vendors

Hospitals Integrated Delivery Systems

ONC

EHR

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ONC
Coordinated Registry Networks (CRNs): evolving portfolio

National
• Ortho CRN
• Vascular CRN – VISION
• Cardiac CRN (will include TVT)
• Neurology CRN – DAISI
• Gastrointestinal CRN – Obesity
• SPARED CRN – Prostate ablation
• Robotic Surgery CRN
• TMD/TMJ CRN
• Abdominal Hernia CRN Orthopedics CRN
• Plastic Surgery – Breast Implants (NBIR/PROFILE)
• Women’s Health Technologies – Uterine Fibroids, Pelvic Floor Disorders, Sterilization Devices

International
• International Consortium Orthopedics Registries (ICOR)
• International Consortium Vascular Registries (ICVR)
• International Consortium of Cardiovascular Registries (ICCR)
• International Collaboration of Breast Registries Activities (I-COBRA)

We currently have 15 national formally launched and 3 other in the making
CRN learning from one another: MDEpiNet launch a Community of Practice (COP)

- CRN sharing lessons learns and best practices.
- Help CRN develop to higher levels of development and production
- Provide focused support to CRN in identified areas
MDEpiNet is launching a Community of Practice (COP) to help CRN mature more quickly

• To create a learning community where CRN can share lessons learns and best practices.
• Help CRN develop to higher levels of development and production
• Provide focused support to CRN in identified areas
MDEpiNet COP Charter: how the COP will work

1. Creation of a repository: resource for CRNs
   - Repository of best practices and lessons learned from others.
   - Sharing this material crucial to CRN development

2. Development of assessment tools
   - Help understand current status of CRN and monitor development

3. Create work plans and work streams/teams
   - That can help CRN mature
   - Specialized teams
1. Creation of a repository

• MDEpiNet proposed to create a web based tool for CRN to share best practices and lessons learned

• All CRN have something to contribute
2. Self Assessment – document capacity

1. IMDRF Domains – capacity to produce
2. Add sustainability (to accommodate the US context)
3. Assessment will be collaborative
   - An assessment tool is available in draft and will be developed with the CRN
   - Not used to judge CRN
4. Used to create a work plan
5. Assessment tool can also be used to monitor progress of the CRNs
Domains* of maturity for CRN

- Producing evidence used by multiple stakeholders
  - Routine use of CRN for device evaluation, used by multiple stakeholders

- Data
  - Policies implemented for core data elements, data quality, interoperability, UDI and informatics (embedded in clinical systems)

- Governance
  - Governance between partners established in writing, with NESTcc, patient engagement policy implemented, transparency and operational SOP implemented

- Methods
  - Well documented and vetted methods for linkage, data sharing, matching, analytical approaches with ongoing research

- TPLC application
  - Capacity expends to nesting clinical trials

- Sustainability
  - Routine and stable revenue generated, business model in place

* Building on IMDRF domains
Current status of CRN Assessment

• We did a preliminary assessment of each CRN based on documentation we have as an exercise to help develop the instrument.
• There is a lot of variation in both capacity and organizational maturity
• NOT used to judge or rank
• The use to engage CRN in a dialogue to help them develop
3. Create work plans and work streams to support CRN development

– Work plans should be created to help the development of each CRN

– Work streams are teams of experts that will work with CRN to help identify needs and work with them towards maturation

– Specialized teams that build on existing effort
  • e.g., The informatics team in MDEpiNet has already created a large part of a repository and is working with some CRNs
  • Other teams that address the areas set out in the various domains need to be created, e.g., sustainability team
MDEpiNet

- Existing MDEpiNet Chapter
- Future MDEpiNet Chapter
- Academic Centers
- Data Sources
Example: International Consortium of Orthopedic Registries (ICOR)

**Partnership:**
29 Registries, - Over 5,200,000 implants

**UDI Promotion:**
Global Clinically-Meaningful Attributes Database for Hips and Knees

**Methods:**
Common Data Model to combine and de-identify data

- Comparative effectiveness / safety studies (27 papers published in JBJS,)
- Catalyzed the development of ICOR-USA and Ortho CRN
- Informed the International Medical Device Regulators Forum (IMDRF) Registry Working Group
- Served as a model for new International Consortia of Vascular, Transcatheter Valve, and Breast Implant registries
CRN Build on International Models and Standards

“Organized system that continuously and consistently collects relevant data in conjunction with routine clinical care, evaluates meaningful outcomes and comprehensively covers the population defined by exposure to particular device(s) at a reasonably generalizable scale (e.g. international, national, regional, and health system)’ with a primary aim to improve the quality of patient care”.

The IMDRF definition approximates the definition of CRN.
Key Registry Attributes

- **DEVICE**: The registry contains sufficient information to uniquely identify the device. Ideally, the unique device identifier would be included, but when the UDI is not available, the registry would include a combination of identifiers (catalog, number, manufacturer, description) that, in combination, will assist in uniquely identifying the device.

- **QUALITY IMPROVEMENT SYSTEM**: The registry is part of a health care delivery quality improvement system or evolving into one as device technologies are diffused into practice and need continuing evaluation (including outlier identification).

- **BENEFICIAL CHANGE**: The registry has established mechanisms to bring about beneficial change in health care delivery through stakeholder participation, ownership and integration into the relevant health care systems.

- **EFFICIENCY**: The registry is embedded in the health care delivery system so that data collection occurs as part of care delivery (i.e., not overly burdensome, not highly complicated, not overly costly, etc.) and integrated with work flow of clinical teams.

- **ACTIONABLE DATA**: The registry provides actionable information in a relevant and timely manner to decision makers.

- **TRANSPARENCY**: The governance structure, data access, and analytical processes of the registry are transparent

- **LINKABILITY**: Information in the registry can be linked with other data sources for enhancement including adequate follow up achievement.

- **TOTAL DEVICE LIFE-CYCLE**: The registry can serve as infrastructure for seamless integration of evidence throughout the device life cycle.
Thank you
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