

MedTech Forum 2022

International Data Transfers

Health Data Considerations

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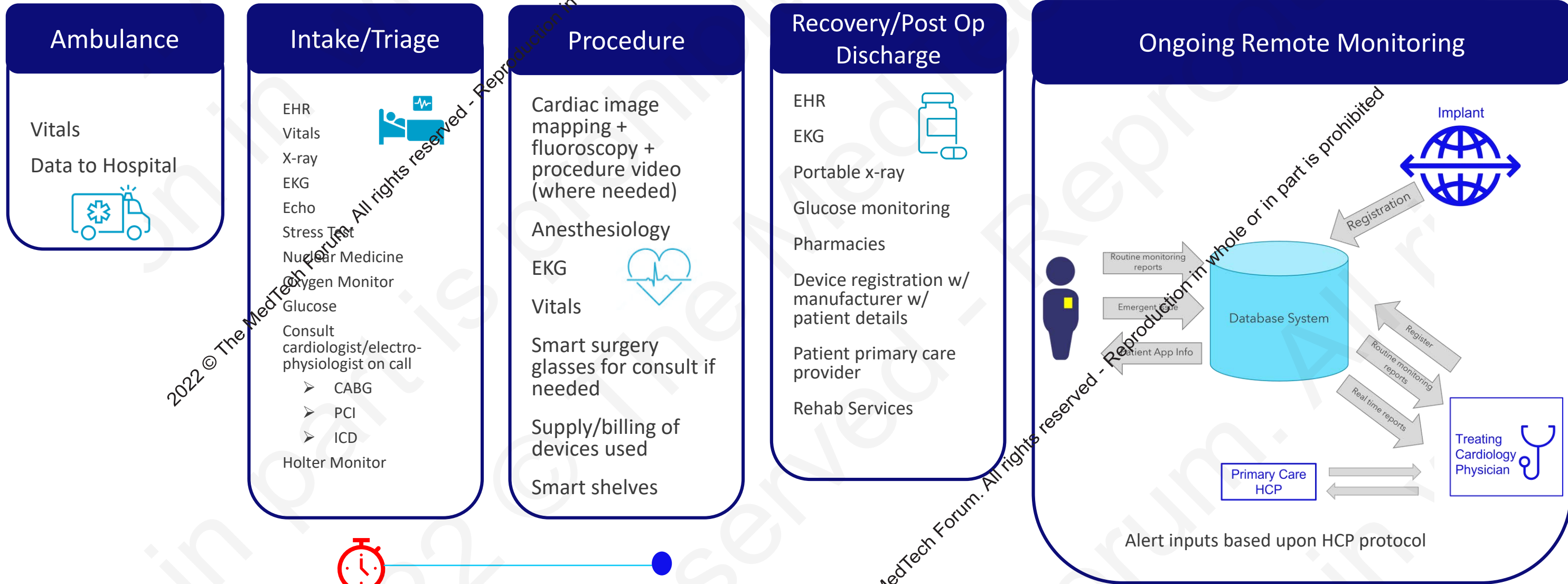
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Future Health Data Attributes

Digital ◦ Portable ◦ Interconnected ◦ Dynamic ◦ Flowing across borders

Cardiovascular disease is the #1 cause of death in the world

Heart Attack Scenario



 "door to treatment time"

*<https://www.who.int/news-room/fact-sheets/detail/the-top-10-causes-of-death>

Stroke Scenario

Stroke is in the EU a leading cause of adult disability and the second most common cause of death*


Stroke

Cannot speak; unresponsive




Ambulance

Stroke assessment
Access patient medical records if possible
Video to neurointerventional radiologist/AI
Stroke center or closest
Data on iPad
Link/Afib monitor




Diagnosis/Triage

CT
Connect EMR data to EHR
Registration
Patient records
Various diagnostic tests
Vessel wall imaging
Cardiac imaging
Cardiac monitoring
Telemetry




Procedures ICU (assume ischemic clot)

CT (multiple)
Liver function
Anesthesiology
EMR
Brain mapping
MRI
Vitals
Supply/smart shelves
Cardiologist



Ongoing treatment/monitoring

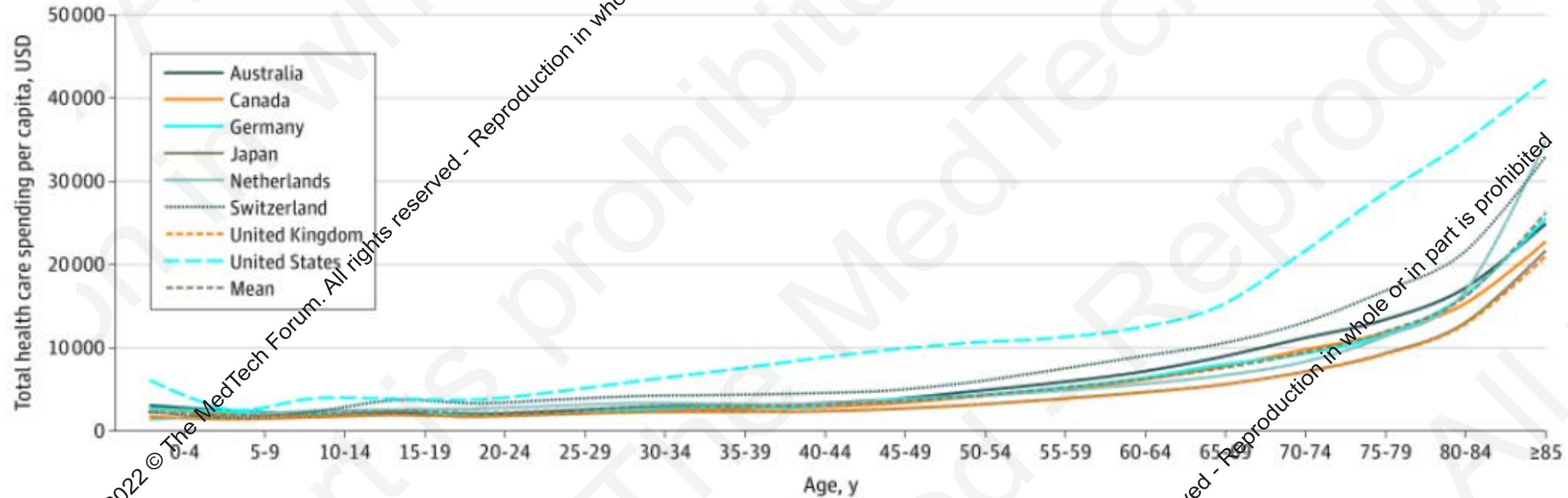
EMR
Relab scheduling
Heart monitor
Pharma order
Primary care doctor
Payors



* <https://www.ahajournals.org/doi/10.1161/STROKEAHA.120.029606>

Who are the patients we are talking about?

Figure.



Per Capita Health Care Spending by Age Group in 8 High-Income Countries in 2015

Spending is purchasing power parity-adjusted. The mean includes all countries except the US. USD indicates US dollars.

Spending by Age in 8 High-Income Countries. *JAMA Netw Open*. 2020;3(8):e2014688. Published 2020 Aug 3.

doi:10.1001/jamanetworkopen.2020.14688



**MedTech Europe
Setting the Stage – U.S.
Privacy Law and
International Transfers**
David Peloquin

Overview of U.S. Privacy Laws

- Sectoral Approach at Federal Level

- Federal Level

Health Data
(e.g., Health Data, Substance Abuse Records, Research Data)

Financial Data
(e.g., Gramm-Leach-Bliley, Fair Credit Reporting Act)

Consumer Data
(e.g., Federal Trade Commission, COPPA)

- State Level

- Historically also had sectoral approach
 - Trend toward omnibus approach

Omnibus State Laws
CCPA/CPRA, VCDPA, CPA, UCPA, CTDPA

HIPAA – Scope of Regulations

- Health Insurance Portability and Accountability Act of 1996 (HIPAA) is most well-known health privacy law in U.S.
- Implemented through three key sets of regulations
 - **Privacy Rule**
 - Requires all **covered entities** and **business associates** to implement certain policies and procedures to protect the privacy of **Protected Health Information**, or **PHI**
 - **Security Rule**
 - Requires the adoption of administrative, technical and physical safeguards to protect the security of electronic PHI
 - **Breach Notification Rule**
 - Requires notification in the event of breaches of unsecured PHI

HIPAA – Covered Entities & Business Associates

- HIPAA has **limited application**
- HIPAA applies only to “**covered entities**,” including:
 - health plans (e.g., health insurance companies),
 - health care clearinghouses (assist with health care claims), and
 - health care providers who transmit HIPAA-covered transactions
- “**Business associates**,” which are persons who
 - On behalf of a covered entity, create, receive, maintain, or transmit PHI for certain functions or activities regulated by HIPAA (e.g., claims processing, utilization review, billing, practice management), or
 - Provide legal, actuarial, accounting, consulting, data aggregation, management, administrative, accreditation, or financial services to or for a covered entity requiring disclosure of PHI

International Transfers

- Despite protections offered to health data in the U.S. by HIPAA, even transfers to HIPAA “covered entities” and “business associates” are subject to the data transfer requirements of GDPR – no HIPAA adequacy decision
- Recent challenges for medical device manufacturers transferring data to U.S. include:
 - Conducting data transfer impact assessments for each transfer
 - Updating existing contracts to use revised Standard Contractual Clauses by December 2022
 - Amending Standard Contractual Clauses to include United Kingdom appendix
 - Onward transfers to entities that have legal barriers to signing standard contractual clauses (e.g., public universities or federal government agencies (e.g., National Institutes of Health))

Schrems II: Why was Privacy Shield invalid?

- In *Schrems II*, the CJEU focused on Section 702 FISA and Executive Order 12333
 - The Foreign Intelligence Surveillance Act of 1978 (FISA) regulates certain types of foreign intelligence collection.
 - Section 702 allows the Attorney General and Director of National Intelligence to direct an “electronic communication service provider” to provide assistance in accessing communications of overseas individuals.
- Executive Order 12333 governs intelligence collection overseas and has been used to organize programs that collect communications transmitted over trans-Atlantic wires.

What is an Executive Order?

- Executive Orders permit the president to direct federal agencies to operate in a certain way. Carries the force of law.
- Executive Orders are issued by the President. An incumbent President has the power to revoke an Executive Order issued by a predecessor
- Congress also has the power to overturn an Executive Order by passing legislation that invalidates it.
- Courts have the power to stay enforcement or ultimately overturn an Executive Order that is found to be beyond the President’s constitutional authority.

New Trans-Atlantic Data Privacy Framework

- Announced March 25, 2022
- Agreement “in principle” between the U.S. government and the European Commission on a framework for trans-Atlantic data sharing

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New Framework for Health Data

- Consider framework that takes lessons learned from GDPR and recent U.S. privacy law developments to guide future legislative developments globally
- Why is a new regime needed for health data sharing?
 - Jurisdictions worldwide adopting new data privacy legislation
 - Current data privacy regimes have certain shortcomings
 - Four years of practical experience interpreting and applying GDPR have revealed challenges for the health care community globally
 - Establishing bases for processing
 - Determining when data are anonymized vs. pseudonymized
 - Defining entities as controllers and processors
 - Providing effective notice to patients
 - Responding to data subject rights requests
 - Legitimizing cross-border transfers of personal data
 - Lessons learned provide insight to future data privacy regimes

New Framework for Health Data

- Why is healthcare different?
 - Treatment often involves coordination of healthcare providers across various geographies
 - Telemedicine permits remote consultations
 - Data from devices may be analyzed in multiple countries
 - Diagnostics often occurs at centralized locations
 - Clinical trials are frequently conducted in multiple jurisdictions
 - Competent authorities recognize importance of multi-national trials
 - Jurisdictions lacking clear basis to process and transfer health data may be disfavored locations for future trials
 - RWE/RWD requires pooling of data sets from multiple jurisdictions

Potential New Framework to Address

- Clear Definition of “Health Data” with tailored regulations
- Pre-defined responsible “permissible uses” such as:
 - Diagnosis & Treatment
 - Research & Innovation
 - Public Health
 - Payment, Operations and Quality Improvement
 - Product Quality and Medical Vigilance/Safety Monitoring
 - Reimbursement and Outcomes Evaluation
- Streamlined International Data Sharing

Potential New Framework Path Forward

- Lawful basis for Processing of Health Data
- Openness and Transparency
- Security Safeguards
- Data Minimization
- Individual Participation
- Accountability
- International Health Data Transfers

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