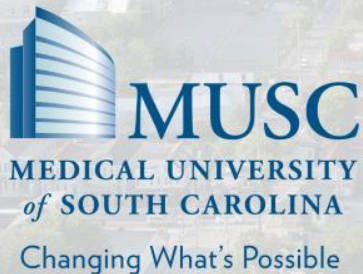


The EHR: To Be or Not To Be

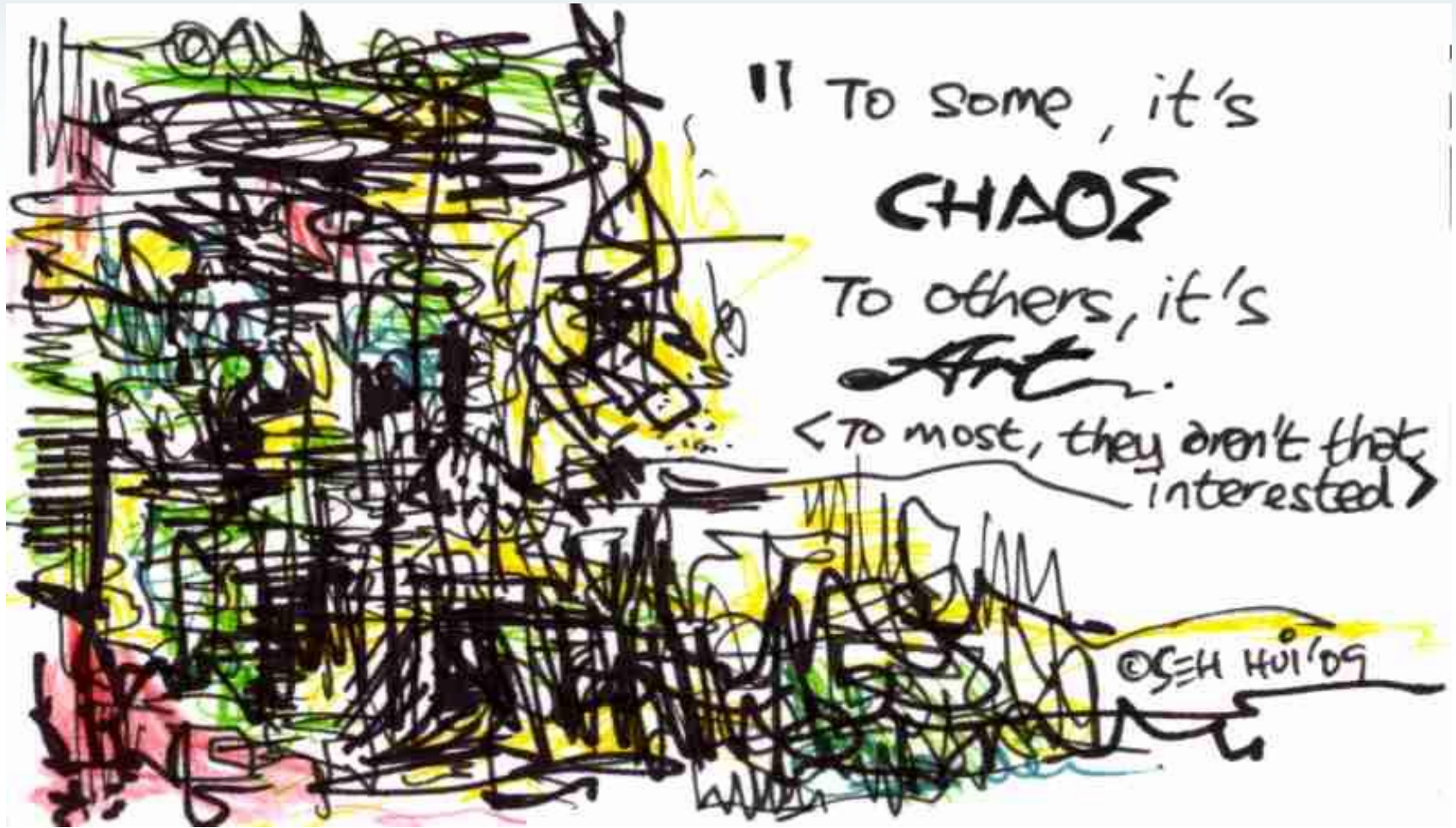
(part of the Legal Medical Record)

For AMDIS 2016



Robert Warren, MD, PhD, MPH
Chief Medical Information Officer

The Medical Record ...



Why should you care ??

CHAOS...

Clinical Research

Legal Liability & e-discovery

Release of Information

Continuity of Patient Care

Integrity & Preservation

LMR amendment per HIPAA



Unsolicited External data

Inside the EHR:

Technical system data
(not patient specific)

Designated
Record Set (DRS)

Legal Medical
Record (LMR)

Patient
Research
Data

Other Patient-Specific
Information (OPSI)

**LMR, DRS, and OPSI
must be very carefully defined in policy
with Legal and Compliance partnership**

Outside the EHR:

Other information systems
(including filing cabinets)



Legal Medical Record and Designated Record Set

Primary, direct documentation of our care of patients in our own care “locations” (per our own Consent to Treat)

LMR:	DRS:
<ul style="list-style-type: none">• Frontline documentation of healthcare services provided by the organization and providers• “Official” medical record for evidentiary purposes and usual response to ROI request• Preserved according to state law, e.g. 10 years• Subject to HIPAA request for amendment	<ul style="list-style-type: none">• Includes the LMR• Supporting clinical information, typically “source” data – e.g. PACS, GI• Other encounter-related data<ul style="list-style-type: none">• Scheduling, billing, etc.



Other Patient-Specific Information (OPSI)

not in LMR or DRS

Retention (or not) of OPSI is a matter of hospital policy unless required by state law.

But if available: discoverable and subject to subpoena

- Information indirectly supportive of specific, best quality care at MUSC
 - Decision-support tools
 - Alerts & guidelines, references, coding and CDI queries
 - Aggregated information
 - Worksheets, worklists, “Kardex”, handoff reports
 - Never finalized, temporary patient-specific information
 - Sticky notes
 - Pended orders and notes
 - Original transcription



Other Patient-Specific Information (OPSI)

- Billing information for services provided at “St Elsewhere” by contracted MUSC providers – e.g. tele-stroke consults
 - Supporting info could include “St Elsewhere’s” medical records, authored by MUSC providers
- Unsolicited, external documents, including un-reviewed clinical information, e.g. attached to or sent to “support” a referral
- MUSC clinical research data that is NOT and does not impact current medical care



Scenario:

External, unsolicited documentation



Referral

- Could be scanned, faxed, or attached to electronic referrals
- Overwhelming volume of administrative and clinical data

MUSC Policy:

- *Documents/ images coming from an external source are excluded from the LMR & DRS, unless designated by provider order provider for inclusion*
- *Until so designated in whole or part, external unsolicited data is OPSI, that will be purged 90 days after receipt.*



Scenario:

What to do about Clinical Research and the EHR?

Research data that is or impacts current clinical care is a part of the LMR/DRS (consistent with JCAH regulation).

- Research data within a given study may be entirely, partially or not at all LMR/DRS.
- IRB-approved informed consent must describe those research data that are a part of the LMR/DRS, and those accessible in/via the EHR, including exclusions protected by a Certificate of Confidentiality.
- If LMR/DRS, it is easily accessible in/via the EHR, unless protected by a Certificate of Confidentiality.
- Research OPSI may be included in the EHR, at the PI's request.

Legal Process of “e-discovery”

It's happening ...

- Plaintiff lawyers with EHR experts requesting a “guided tour” of the patient’s electronic record in response to their questions (LMR, DRS and OPSI).
- Examples:
 - Who wrote this note ? When ? When was it signed ? Was it changed ? Who reviewed it ? When ?
 - Did the provider see any alert about this medication order ? What was it? What was her response ?
- Preparation:
 - Clarification of OPSI and retention in policy is essential. Should some OPSI (e.g. alerting data) be routinely purged?
 - Defense team for e-discovery must include well-trained, e-discovery-process-savvy informaticists who answer plaintiff questions specifically without added explanation



Issues and Questions

The EHR is not just software

- ❖ Careful definition of the medical record according to state law
- ❖ Clarification and congruence of health system policies for standardization of clinical care and research documentation
- ❖ Retention of OPSI ?
- ❖ Education of providers
- ❖ Limitations of EHR data models: we need data element labelling as LMR/DRS/OPSI. At best, that should be modifiable at the level of a specific observation.
- ❖ Training of e-discovery teams?
- ❖ **Your questions?? (and comments and solutions)**

