





Master Data Management with GDSN

Work in Progress, Implications and Outlook

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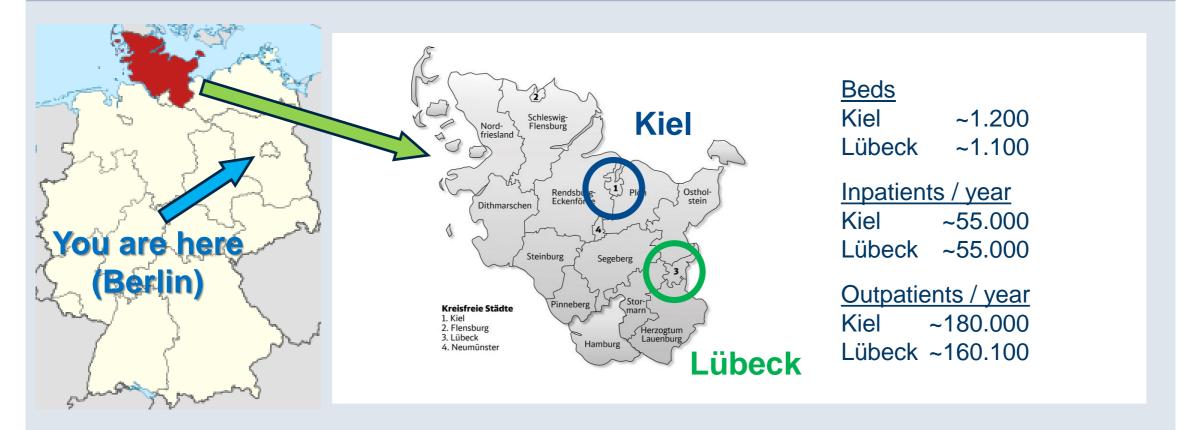
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Schleswig-Holstein & its University Medical Center



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Main Motive for UDI: Patient Safety

- Two prerequisites for safe use of medical devices:
 - Reliably and easily identify the device
 - Know the properties of the device
- Accordingly:
 - Two components of UDI regulations:
 - Device and Production Identifiers
 - Global UDI Database (GUDID) and corresponding databases





UDI can be a blessing for hospitals

- Not only for patient safety
- Also for processes
 - Not only for logistics track & trace
 - Also clinical processes at the point of care
 - Chance to improve revenue







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Streamlining medical processes

- Have in the right place at the right time
 - Patient
 - Providers
 - Appliances
 - Devices & Consumables

Information / knowledge about

- Patient
- Providers
- Appliances
- Devices & Consumables

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- So far the easy part: Defining wishes and requirements
- Now the going gets tough: Implementation







UDI challenges for hospitals

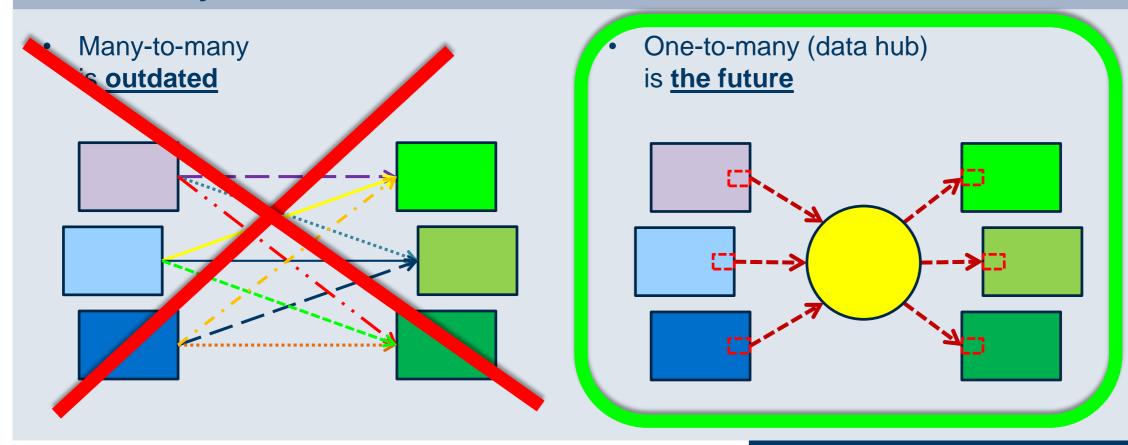
- Availability from external sources
 - timely / up-to-date
 - correct
 - complete (whatever that means, we will come back to that)
- Management within the organisation
 - including quality management
- Data flow within the organisation
 - including display at the point of care
 - including propagation between IT applications







Availability from external sources: Communication



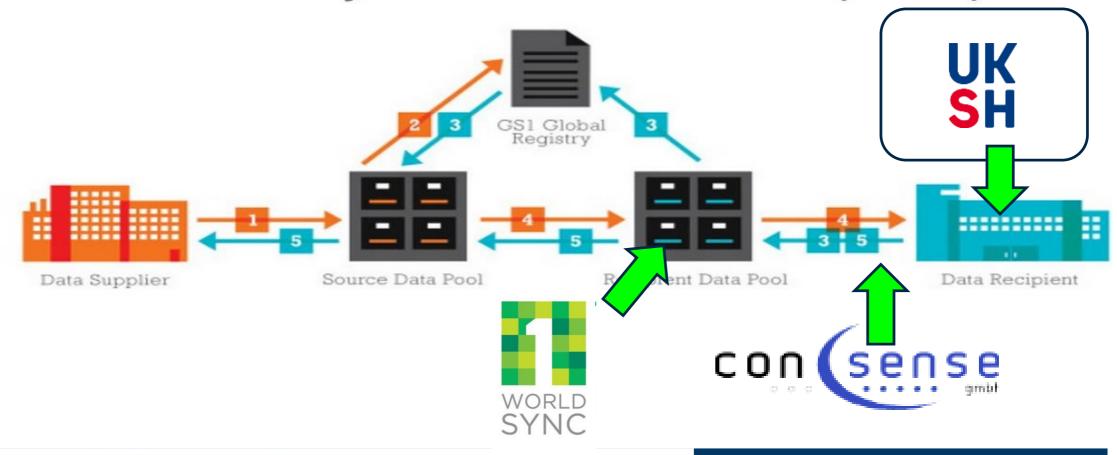
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Global Data Synchronization Network (GDSN)



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Challenges for the UKSH

- We fell behind with our homework
 - Activation of the interface to the GDSN
 - Definition of rules and procedures for Master Data Quality Management
- We have (not too phony) excuses
 - Lack of resources
 - Unexpected culture shocks
 - Now there is content used by clinical staff (= aliens...)
 - Master data are responsible for clinical work flows
 - Change of GPO
- We promise improvement







Master data content

- For logistics and procurement
 - OK, that's the basics
- For clinical aspects
 - This is the area providing a lot of additional value for the healthcare providers







Unique device identifiers for coronary stent () CrossMark postmarket surveillance and research: A report from the Food and Drug Administration Medical Device Epidemiology Network Unique Device Identifier Demonstration

James E. Tcheng, MD, ^a Jay Crowley, MS, ^{b,i} Madris Tomes, MBA, ^{c,i} Terrie L. Reed, MS, ^{d,i} Joseph M. Dudas, MBA, ^e Kweli P. Thompson, MD, ^f Kirk N. Garratt, MD, ^g and Joseph P. Drozda, Jr., MD ^h, on behalf of the MDEpiNet UDI Demonstration Expert Workgroup *Durbam, NC; Santa Barbara, CA; Washington, DC; Rochester, Minneapolis, MN; New York, NY; and Chesterfield, MO*

Conclusions This process for identifying requisite extensions to support the effective use of UDI-associated data should be generalizable. Implementation of a UDI system for medical devices must anticipate both global and device-specific information. (Am Heart J 2014;168:405-413.e2.)

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UDI and Patient Safety: Raising Awareness in Germany



Alliance for Action
on Patient Safety



 Federation of University Medical Centers in Germany

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Thank you for your attention

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