## **Oracle Security**

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## **Agenda**

- ≥ 21 CFR Part 11
- **M**HIPAA
- **☒** Oracle Security

## **Security Challenges**

- ☑ Privacy of Communications
- Granular Access Control

- Is your query result read or modified in transit?

- ☑ Can you support 100,000s of users?
- Is it easy to use for users & administrators?
- ☑ Who is accessing the data from the web?

#### 21 CFR Part 11

Regulations that provide criteria for acceptance by FDA of electronic records, electronic signatures, and handwritten signatures executed to electronic records as equivalent to paper records and handwritten signatures executed on paper

#### **⊠** Requirements:

- Strong Security to ensure the authenticity, integrity, and confidentiality of electronic records.
- Audit Trail
- Operational System Checks
- Electronic Signatures to ensure that the signer cannot readily repudiate he signed record.

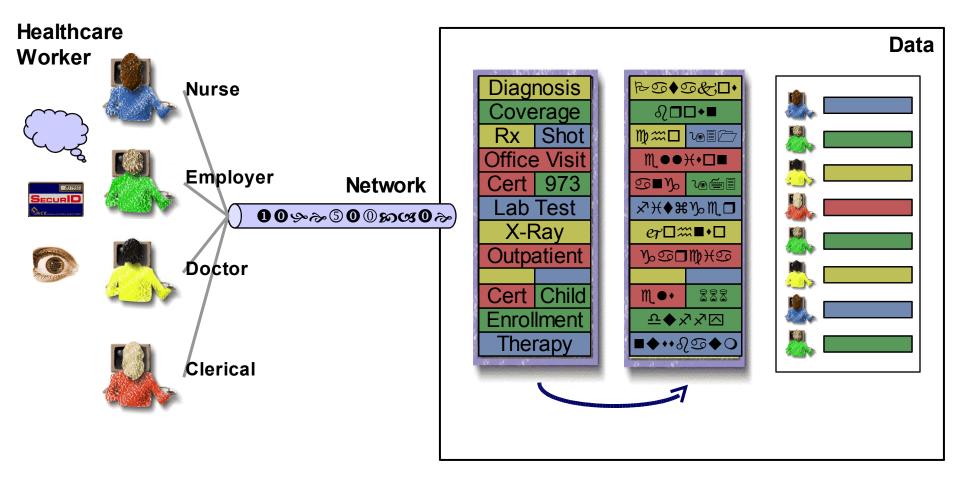
#### What is HIPAA?

- ☑ Health Insurance Portability and Accountability Act
  of 1996, Public Law 104-191 (HIPAA)
  - aka Kennedy-Kassenbaum Bill
- - Privacy Rule: "what" individual health information must be protected
  - Security Rule: "how" healthcare organizations need to protect health-related information
- Noncompliance would put you in jail.

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  ■

#### **Security & Privacy**



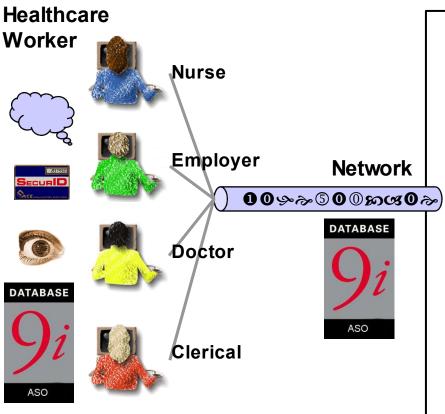
Identify & Authenticate Privacy & integrity of communications

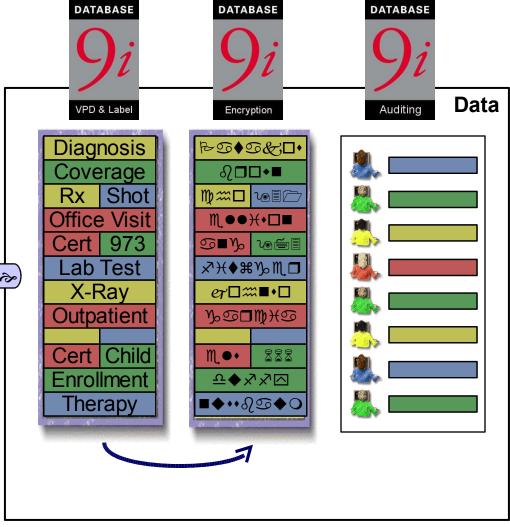
**Access** control

Privacy & integrity of data

Comprehensive auditing

#### **Security & Privacy**





Identify & Authenticate Privacy & integrity of communications

**Access** control

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#### Identification& Authentication

- - name/password
- - Smart cards (e.g. Secure ID card, AcitivCard)
  - X.509v3 compliant digital certificates over SSL
- Something you are
  - Biometric (e.g. fingerprint reader)
- - Kerberos, RADIUS, DCE.

## **Privacy & Integrity of Communications**

- - Oracle Advanced Security provides these algorithms to encrypt Oracle Net traffic

Triple DES

RC4

Advanced Encryption Standard

⊠Users do not need to use SSL or digital certificates.

SSL support (standards based encryption)

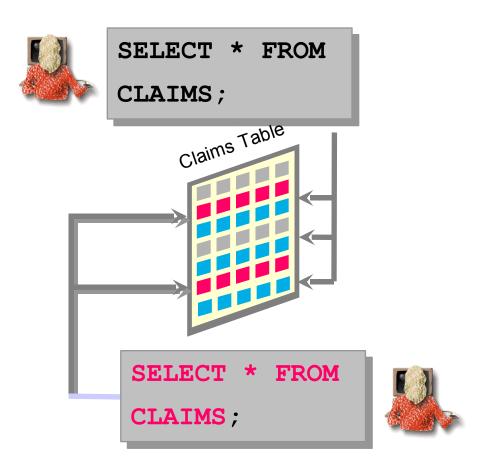
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- Verifies that data have not been tampered with during transmission
- Supports Message Digest 5 (MD5) and Security Hashing Algorithm (SHA-1).

#### **Access Control – Protect Data**

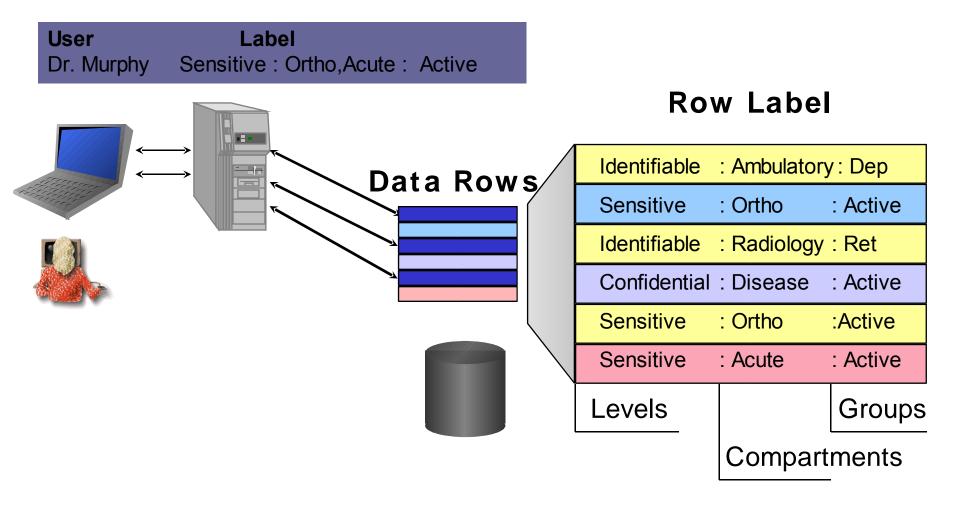
- **▼Virtual Private Database**
- **区**Label Security
- **Selective Data Encryption** Selective Data Encryption

### Virtual Private Database (VPD)



- Enables, within a single database, per-user data access with the assurance of physical data separation
- Associate security policies implemented by functions with tables or views
- Server automatically enforces security policies no matter how data is accessed

## **Oracle Label Security**



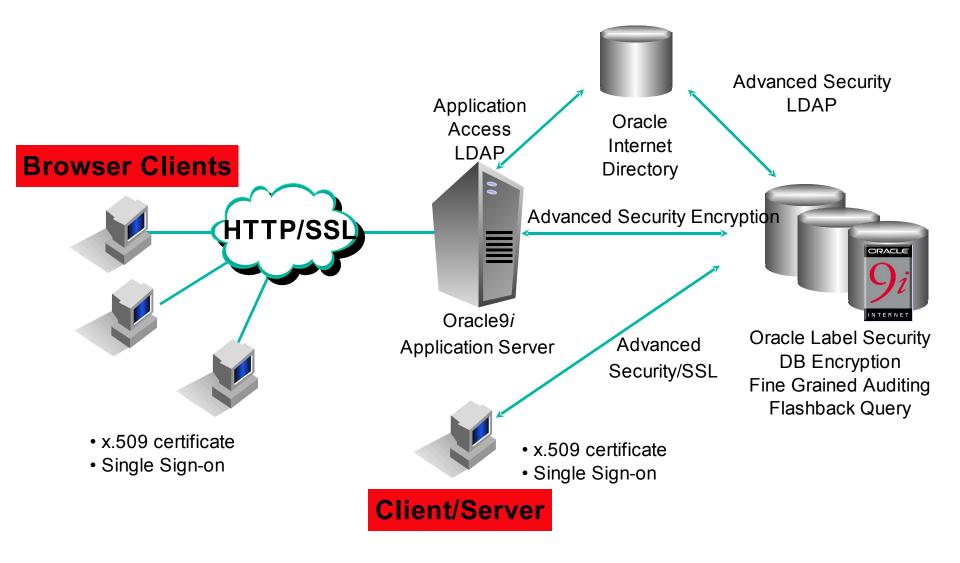
### **Selective Data Encryption**

- ☑Protect select data via encryption in the database
- **区**Examples:
  - Credit card numbers, patient's SSN
- ☑DBMS\_OBFUSCATION\_TOOLKIT package
  - Supports Data Encryption Standard (DES) and 3DES algorithms
  - Supports MD5 to ensure data integrity

## **Auditing - Provides Accountability**

- **区**Ustomizes auditing with triggers
- Enables organizations to define specific audit policies that can alert administrators and serve as an intrusion detection system.
- □ Captures exact SQL statement. Together with Flashback Query, auditing can recreate the exact records returned to a user.

#### **Oracle Secure 3-Tier Architecture**



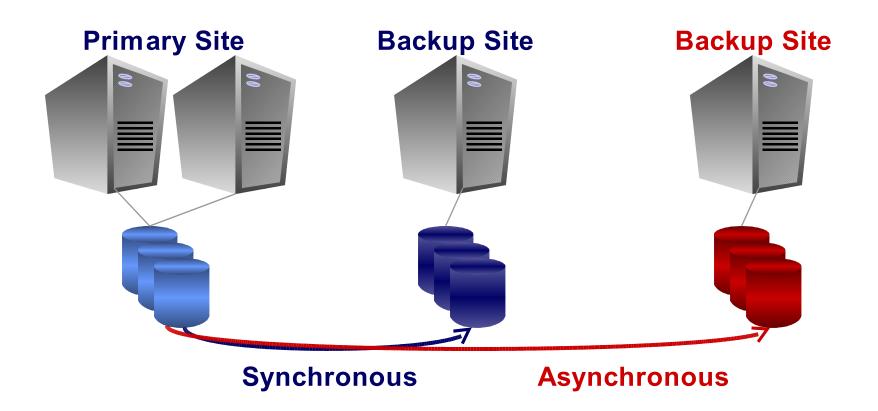
## **Security Feature Comparison**

Security Features	Oracle	IBM DB2	Microsoft SS2000
Virtual Private Database	Yes	No	No
Label-based Access Control	Yes	No	No
Data Encryption	Yes	Limited	No
Fine-grained Auditing	Yes	No	No

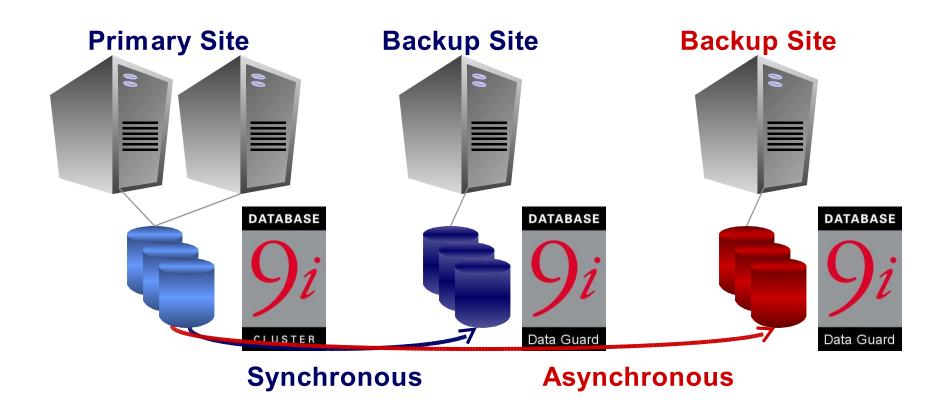
## 15 Independent Security Evaluations

Security Criteria	Oracle	IBM DB2	Microsoft SS2000
TCSEC, Level B1	1	0	0
TCSEC, Level C2	1	0	1
ITSEC, levels E3/F-C2	3	0	0
ITSEC, levels E3/F-B1	3	0	0
Common Criteria, level EAL-4	4	0	0
Russian Criteria, levels III, IV	2	0	0
FIPS 140-1, level 2	1	0	0
TOTAL	15	0	1

## **Availability & Business Continuity**



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### **PCASSO** Project

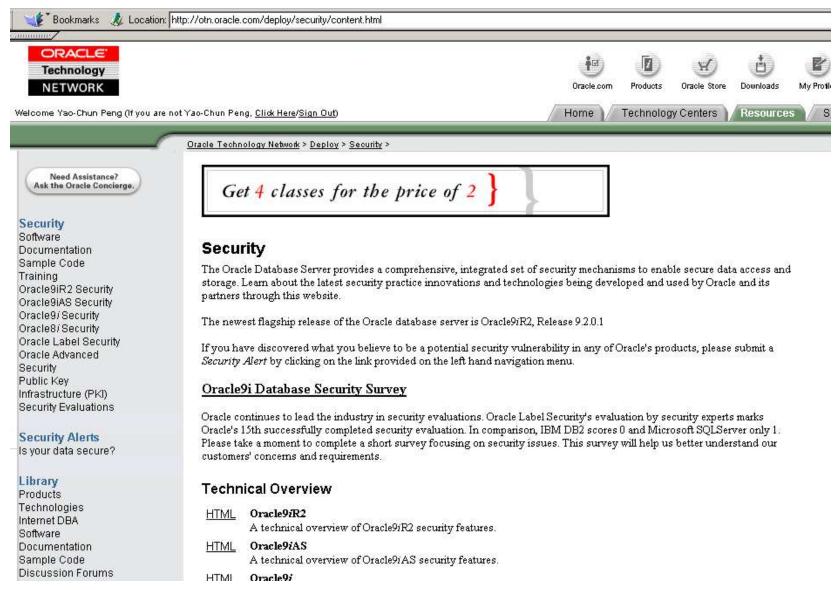
(Patient Centered Access to Secure Systems Online)

- SAIC and UCSD − Patient and health care providers access patients' complete medical records over the Internet
- **≥**178,000 patients
- In defining those levels, we needed to separately protect highly sensitive information that − by law-requires special protection. ...Label-based access control is ideal for this purpose.
  - Dixie Baker, corporate VP of technology and CTO for SAIC's healthcare practice

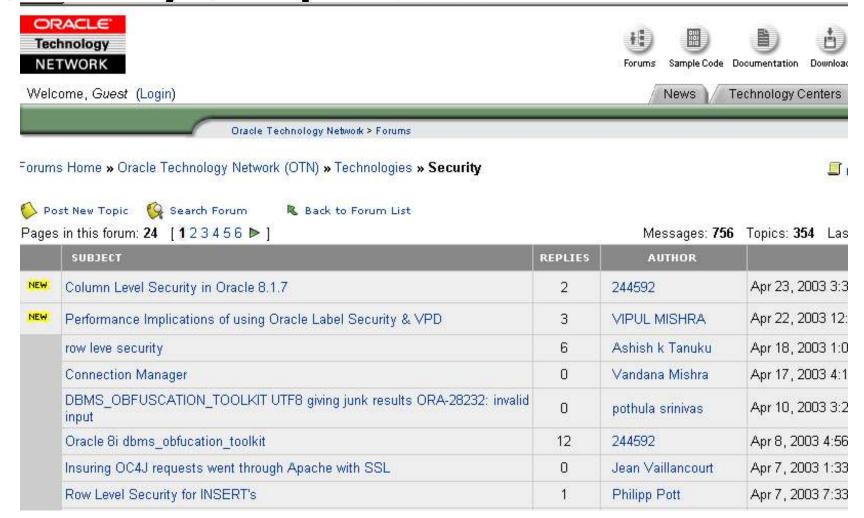
## Summary: Oracle features to achieve HIPAA goals

Oracle9i Features	Data Privacy	Data Security	User Identity	Auditing
Network Encryption	Yes	Yes		
Database Encryption	Yes	Yes		
Restricts Data Access	Yes	Yes		
Data Sensitivity Labels	Yes	Yes		
Comprehensive Auditing	Yes	Yes		Yes
User Management	Yes	Yes	Yes	
Single Sign-on	Yes	Yes	Yes	
User Authentication	Yes	Yes	Yes	
Independent Evaluation	Yes	Yes	Yes	Yes
Assurance	Yes	Yes	Yes	Yes

#### Resources



## Discussion Forums: Security & Security Sample Code



# Sept 10, 2003 Life Sciences User Group Meeting at Oracle World, San Francisco

#### **Security Presentations:** ■

- Johnson & Johnson,
   Building a Secure Infrastructure with Oracle in Life Sciences - J & J PKI and Secure Connectivity to Oracle
- Massachusetts General Hospital
   Secure Enterprise Access for Phenotypic Research at Mass General Hospital & HIPAA
- Wyeth
   21 CFR Part 11 via Oracle Auditing at Wyeth
   Research

#### For More Information

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