Dataprotection in Hospitals

Bart Van den Bosch

CIO UZ Leuven

March 1, 2011

Dataprotection

- Situation of hospital data protection
- (Fysical security)
- System data protection
  - Availibility & Integrity
  - Confidentiality
- Network security
- Application level data protection

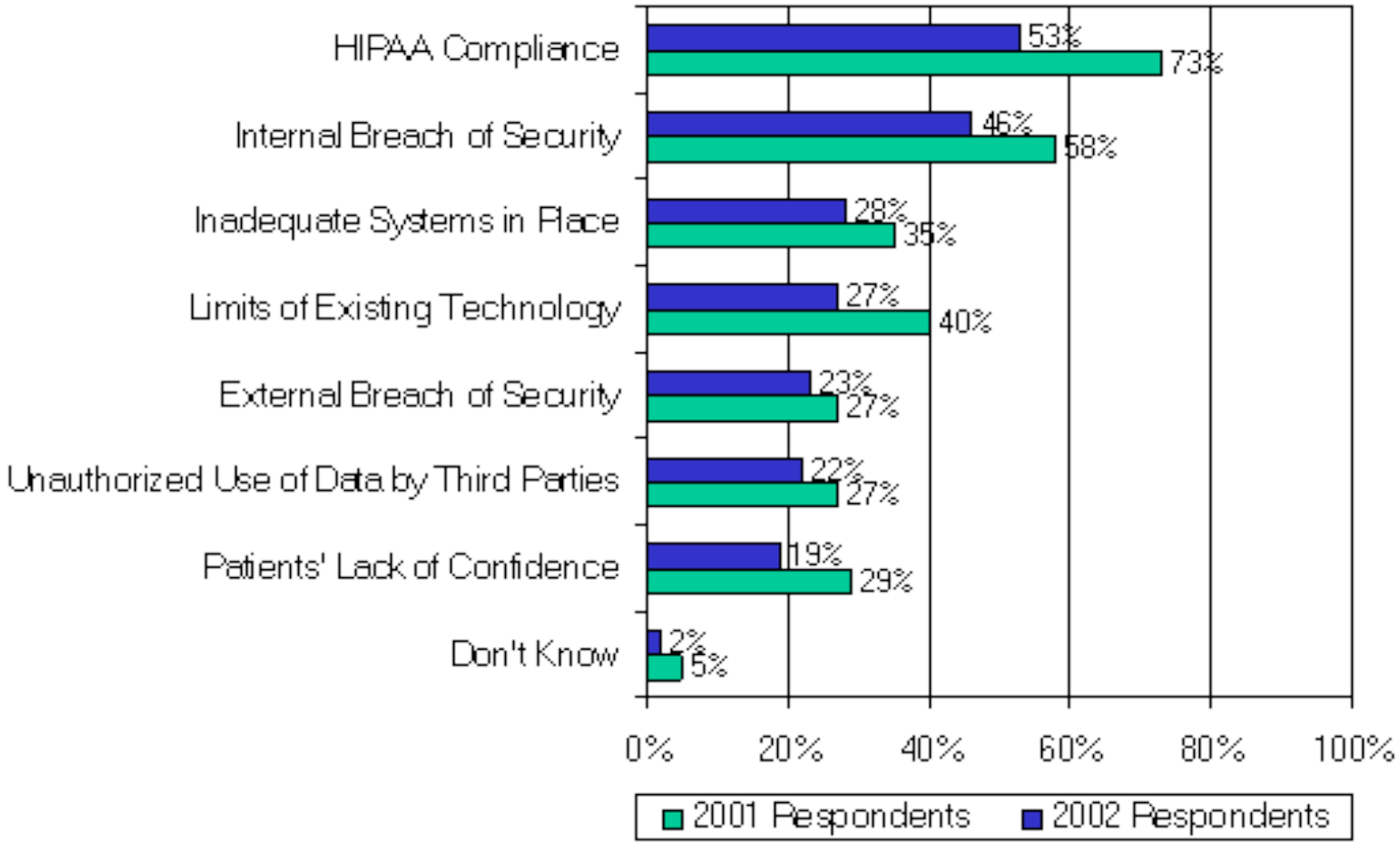
Situation

- Enemy is difficult to define
- Everybody is a VIP to somebody
- Curiosity is the driving factor
  - Everyone is curious to some degree
  - Impossible to screen personnel on curiosity

You can at best control legitimate access,
You can never control legitimate use.

Threats

13th Annual HIMSS Leadership Survey 2002
Top concerns security electronic patient records:



External Threat

"Two years ago *Sunday Times* reporters were able to gain access to the private medical records of Dr Sandy Macara by paying a small fee to a commercial agency."

BMJ 1999;318:1328–31

Physical situation

- Open house: lots of strangers near screens
- No physical separation between patients, personnel, visitors, students or external personnel
- No problem if you carry a suitcase (or two)
- Very complex and constantly shifting access needed
  - Depends on workflow: referrals, (abnormal) results, requests,...
- Nurses have short but frequent bouts of workstation work
- Several users simultaneously on same workstation; one user will switch constantly between different workstations.

Requirements on availability

- Nuclear plant
  - Can not afford to go down
  - During maintenance of plant the hardware and software can also be maintained (days, weeks)
  - Historical data is “historical”
- Hospital
  - 5’ down is not too bad, but hours downtime not allowed.
  - No maintenance window whatsoever (migration!)
  - Historical data becomes acute data when patient is in
  - Data loss not allowed (at least not the first 30 years after the death of the patient)

➔ **Different system contingency plans!**

System data protection: availability

- All storage consolidated on NetApp
- RAID disks with double parity
  - Hot swappable, automatic replacement ordering
- Separate storage clusters for both data and logs (data x 2)
- Problem with clusters
  - Both halves need the same software
  - Corruption in software affects both copies
  - Upgrading the cluster requires taking it down
- Still not possible to upgrade DB software without downtime

Amateurs talk strategy, professionals talk logistics.

- General Norman Schwartzkopf

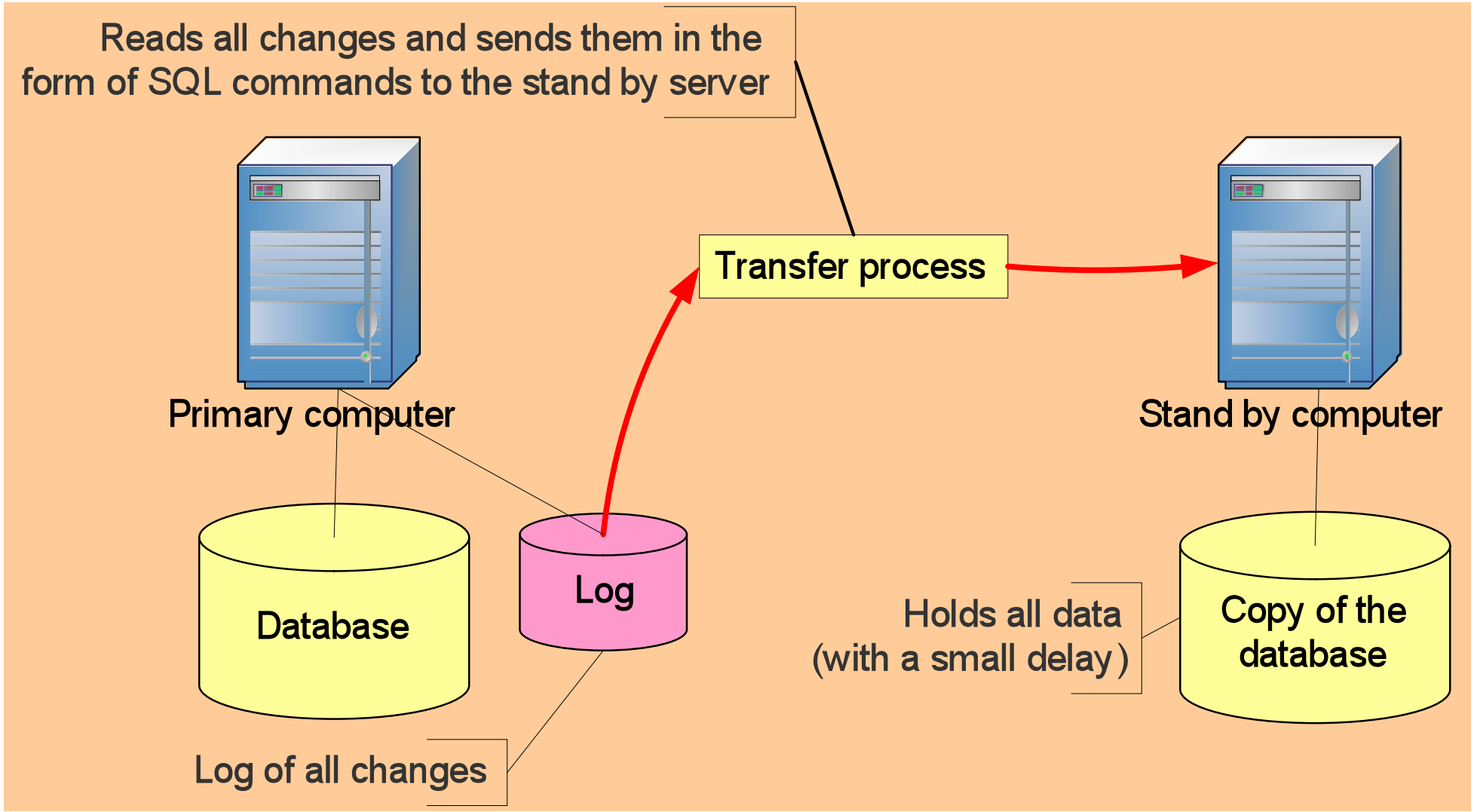
Amateurs talk development, professionals talk migration.

- Prosenior Bart Van den Bosch

Hence:

- Identical configuration in 2d data center: hot standby (data x 4)
  - Production can switch from one data center to the other
- Between data centers: logical data replication (sort of log shipping)
  - Data manipulation reduced to very simple insert, update and delete statements
  - Allows to have different versions of database software in both data centers containing same data!

Replication of a database



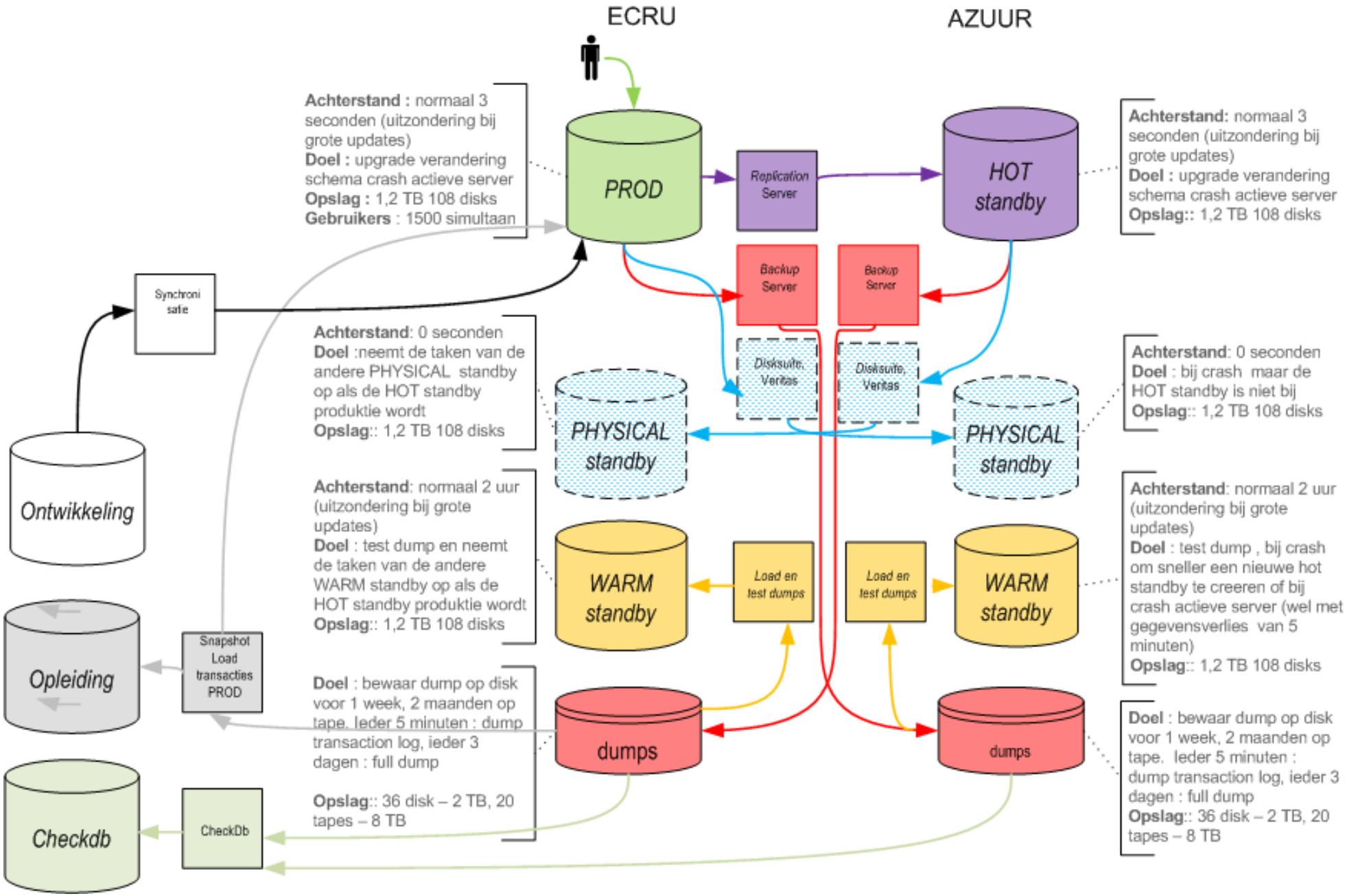
Replication of a database (2)

- Advantage
  - Both servers can run different version of the software
    ➔ reduces unplanned downtime
- Disadvantage
  - Not a simple set up!
  - Standby computer is a passive computer: expensive!
    - Can be used for a limited number of tasks

But...

- Still problems with application bugs that corrupt data
- Programmers going ape...
- Hence: **warm standby** (data x 5)
  - Smaller configuration
  - Loaded with backup of production data
  - Gets all logs applied but with a time delay of ± 6h
- Gives us 6h to detect corruptions
- BONUS: Continuous sanity check of backups & logs
- (BTW: Backup on disk ➔ fast restore (data x 6))

Clinical data protection



Authentication (within hospital)

- (Still) username & password
  - Passwords only 3 months valid
  - Can not be repeated
  - Must be 8 chars long & 2 char sets
  - Parts of 4 chars and more should not be known words
- Why? Ergonomics! All other solutions either insecure or slow...
  - Maybe fingerprint recognition in future?
  - 14.000 fingerprints is BIG for any current system

Confidentiality (database level)

- The usual stuff: database authorisation matrix
  - Expressivity is too low for fine grained access control ➔ done on appl level (see later)
- System logs:
  - We do not have/cannot afford/do not want separate deployment and development teams
  - Programmer actions are logged on system level
  - 4 eyes principle (but within department)

Password policy

- Single sign on: we do not allow separate logins for different applications → if your password is known, others have access to
  - your email, your personal files, your credit accounts, your vacation chart, and (soon) your salary
- Everybody gets a login. There is never a reason to use somebody else's.

Authentication from outside

- Juniper for encryption
- Digipass from Vasco
  - Radius server
- Requires all users to be known and registered
- For patient access: Belgian eID card or “token”

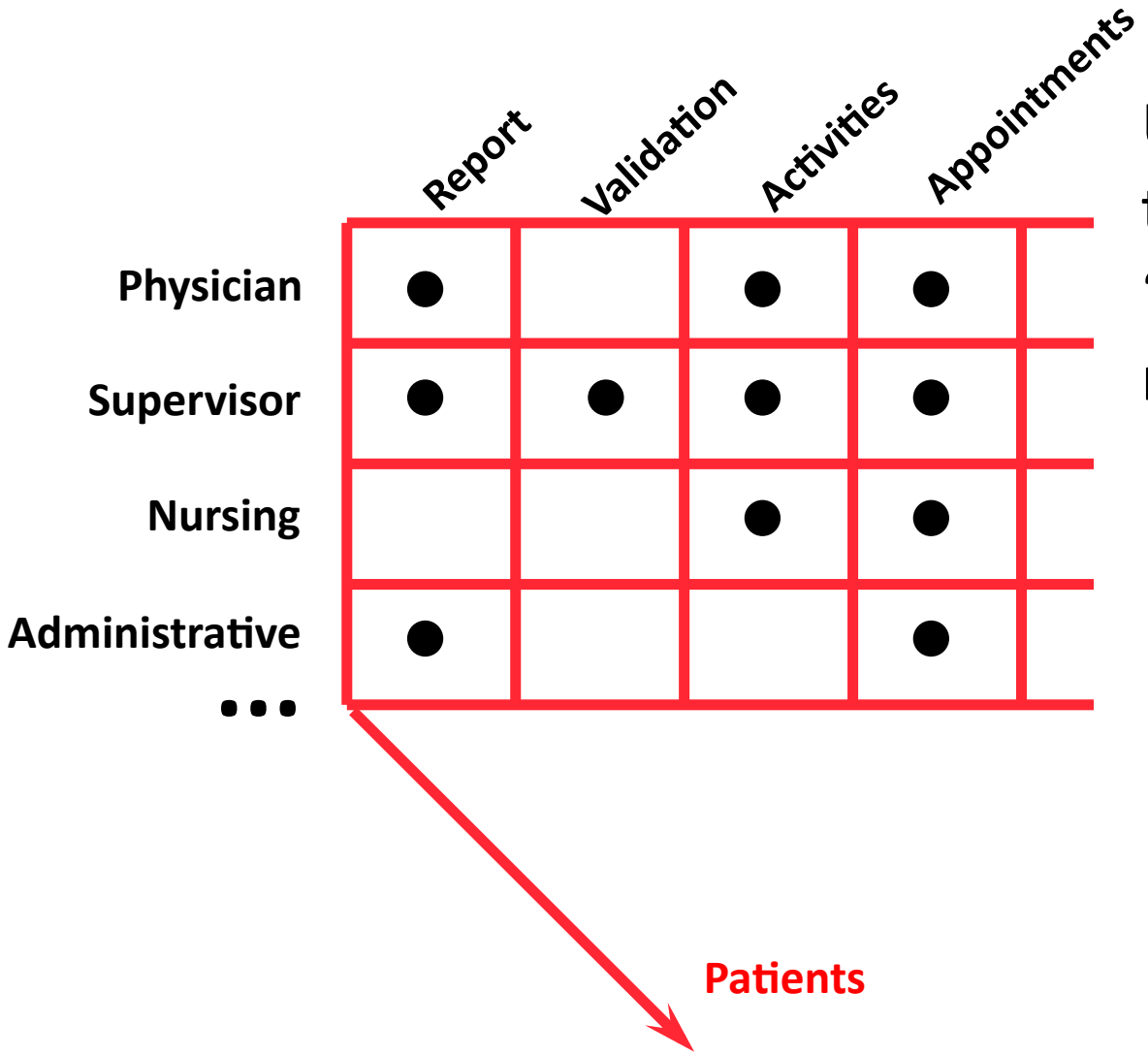
Application level

- Authentication
- Access control
- Logging and audit
- Procedures
- Emergency procedures

Authentication

- ERGONOMICS!!!
- Switch users without stopping application
- Screenblanker after 12 min
  - Same user returns → same windows
  - Other user → most windows close but some censuslists, worklist remain open
- 12 min ← long enough to allow physician to do part of examination
  - In operating room: no screenblanker

Dynamic Access Control



(In many systems this axis is not used)

User must have access to info on a patient "when there is a medical need-to-know".

= if user is involved in treatment

= if contact between user and patient OR

= if appointment planned OR

= if examination request for that user OR...

Fine grained access control

- “Need to know” is not an algorithm
- Is data available to deduce the need to know?
  - Full integration of all systems necessary
    ➔ Full integration of management necessary
  - Deduction only from data already registered, not on intention!
- Emergency access should always be possible

Deducing “the need to know”:

- Location of patient
  - Every physician, nurse,... is associated with a ward and or department
- Is there an active relationship between physician and patient (usually ends with a validated report)
  - Grace period of access after validation
- Appointment planned?
- Operation planned or requested?
- Technical examination planned or requested?
- Request to other physician to look into the case?
- ...

LISA: other access model

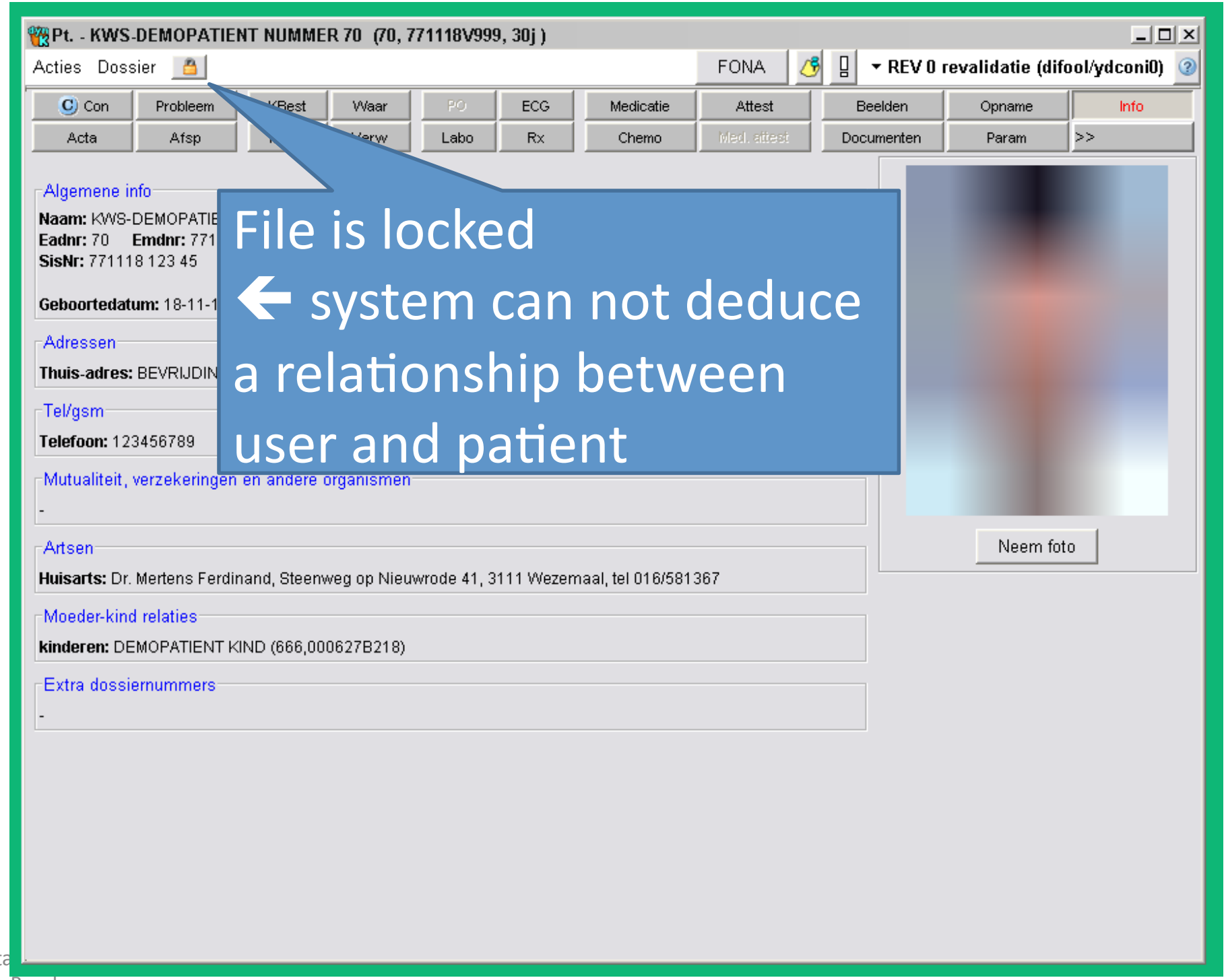
- LISA = Leuvense Internet Samenwerking Artsen
- Referring physicians access the medical file within UZ for their patients
  - Access to complete file, not only reports adressed to them
  - Allows them to give better service to patients and family
- Informed consent necessary: 99.5% of patients signs
  - We do not have the info to deduce “need to know”
  - Less social control
- Used to be “opt in”, currently “opt out”
  - Only for General practitioners

Logs : data level

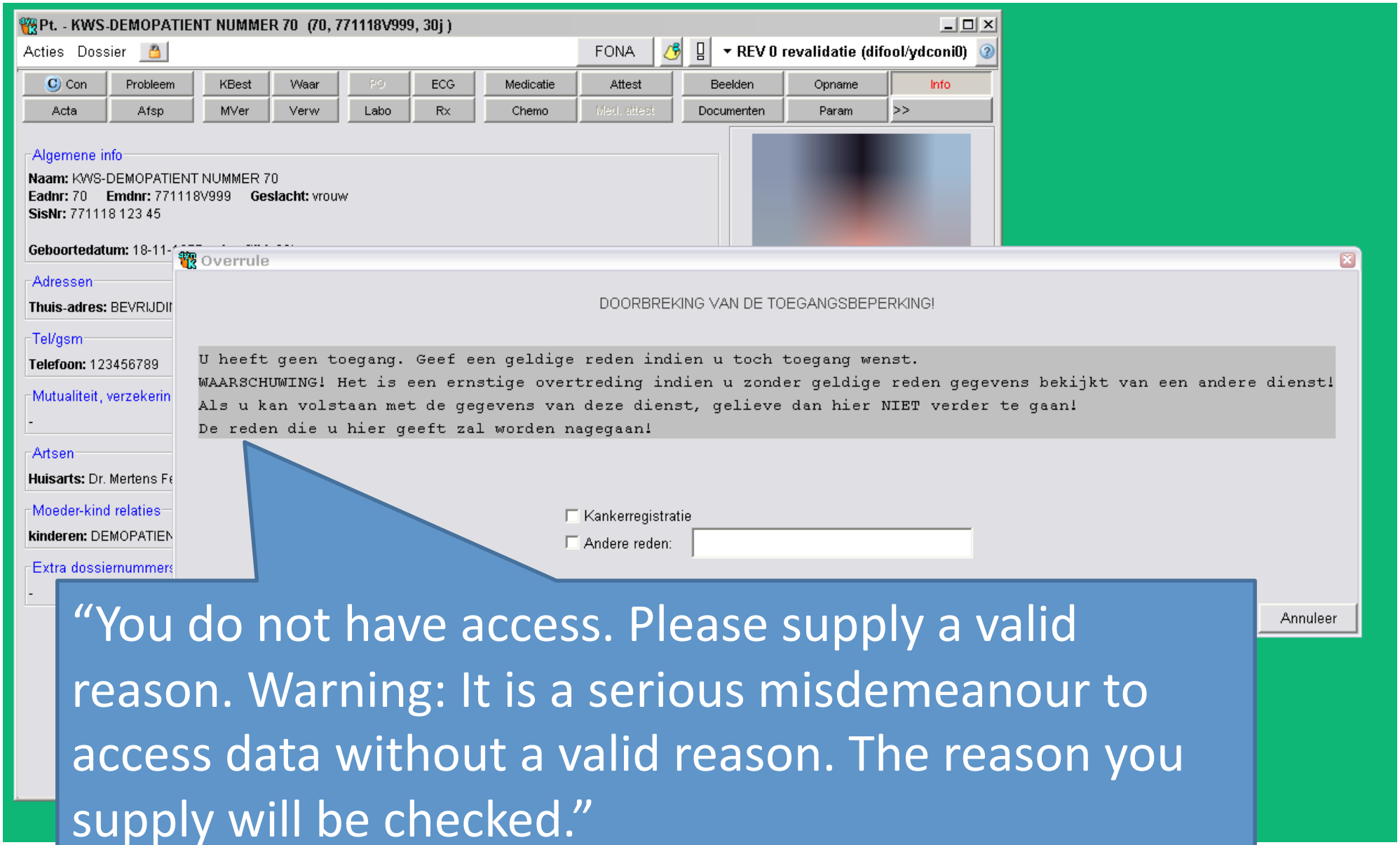
- The Clinical Workstation data model is deletionless
  - Update = logical delete old record + insert corrected record + link between these
  - Delete = logical delete
  - Everything = timestamped + username recorded
- Enforced on database level
- State of data base can be reconstructed to any point in time

Logs: user level

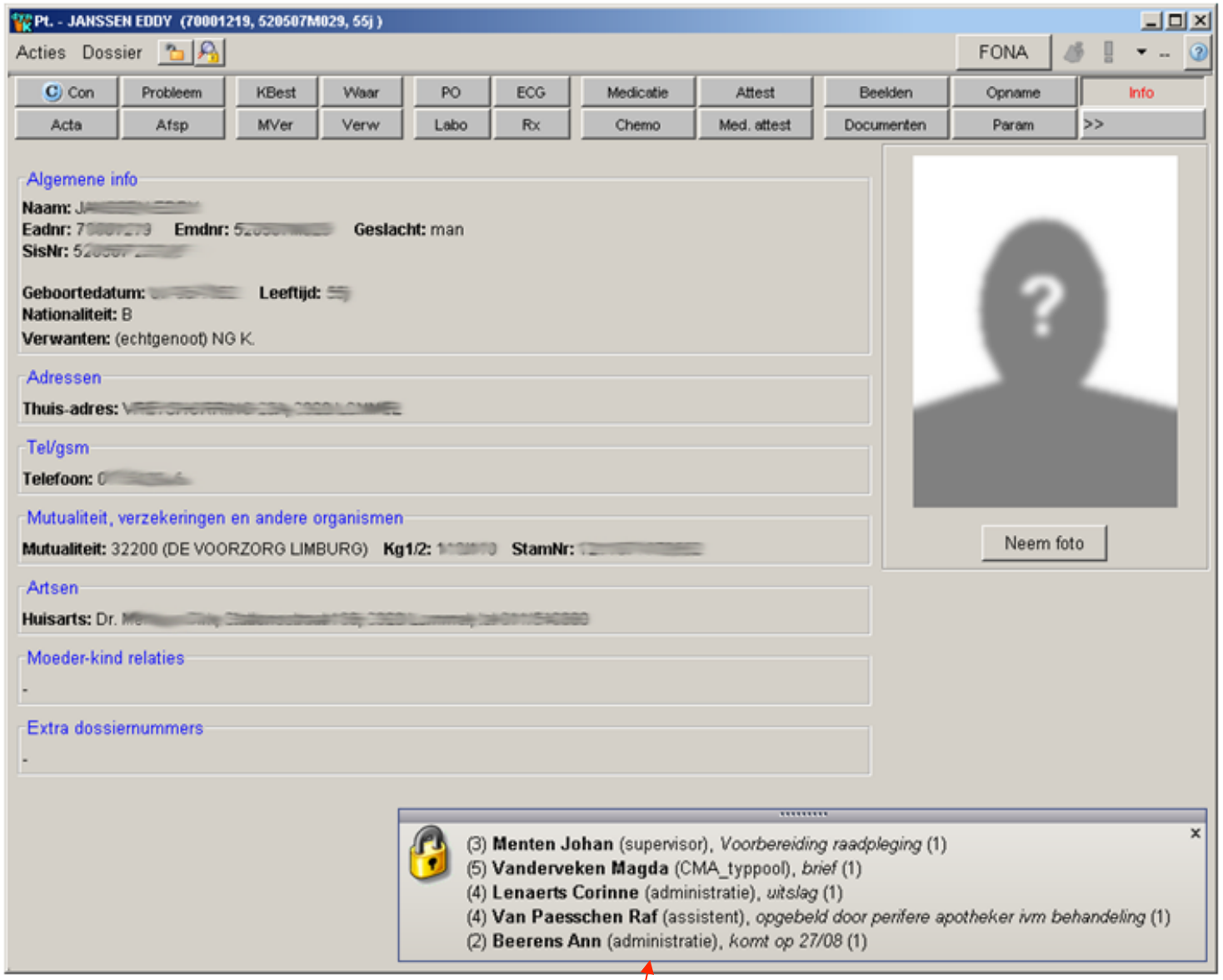
- Access given ONLY AFTER “need to know” for specific patient and user combination is checked
- If OK → normal access, silent logging
- If NOT OK → user has to overrule
  - Reason needs to be given
  - All accesses are logged
  - Treating physicians can see the (overrule) logs for their patients


Pt. - KWS-DEMOPATIENT NUMMER 70 (70, 771118V999, 30j)
Acties Dossier
FONA
REV 0 revalidatie (difool/ydconi0)
Con
Probleem
KBest
Waar
PO
ECG
Medicatie
Attest
Beelden
Opname
Info
Acta
Afsp
Verw
Labo
Rx
Chemo
Med. attest
Documenten
Param
>>
Algemene info
Naam: KWS-DEMOPATIE
Eadnr: 70 Emdnr: 771
SisNr: 771118 123 45
Geboortedatum: 18-11-1
Adressen
Thuis-adres: BEVRIJDIN
Tel/gsm
Telefoon: 123456789
Mutualiteit, verzekeringen en andere organismen
-
Artsen
Huisarts: Dr. Mertens Ferdinand, Steenweg op Nieuwrode 41, 3111 Wezemaal, tel 016/581367
Moeder-kind relaties
kinderen: DEMOPATIENT KIND (666,000627B218)
Extra dossiernummers
-
Neem foto
File is locked
← system can not deduce a relationship between user and patient

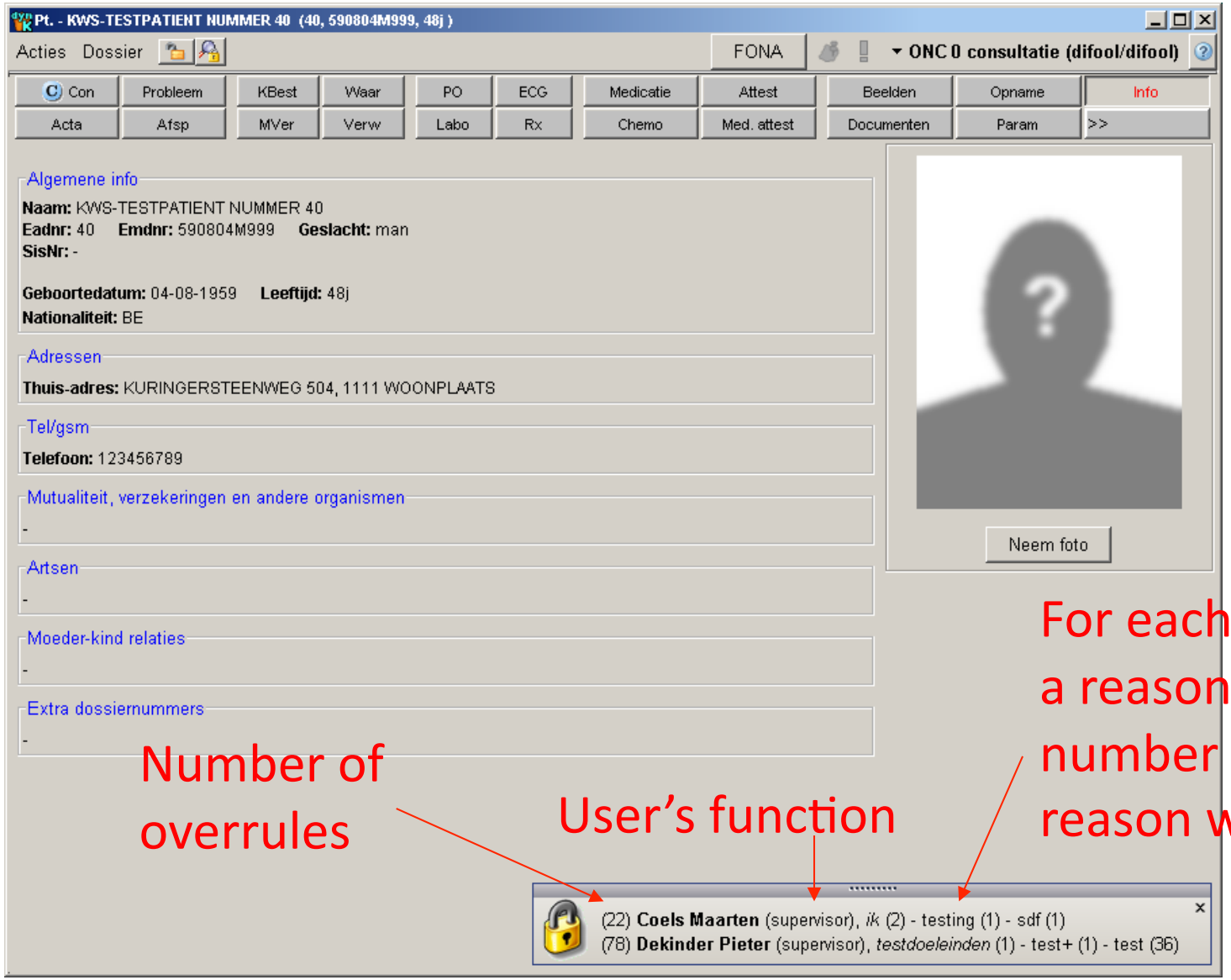
Request for overrule reason



"You do not have access. Please supply a valid reason. Warning: It is a serious misdemeanour to access data without a valid reason. The reason you supply will be checked."



Automatic popup when opening patient file. Disappears automatically after a few seconds (or by closing it)



Number of overrules

User's function

For each overrule where a reason was given, the number of times this reason was used.

The popup shows an overview of the last 100 overrules grouped by user.

On clicking the popup a list is given with details of the overrules.

Overzicht van de gelogde toegangen

Toon laatste 100 overrules

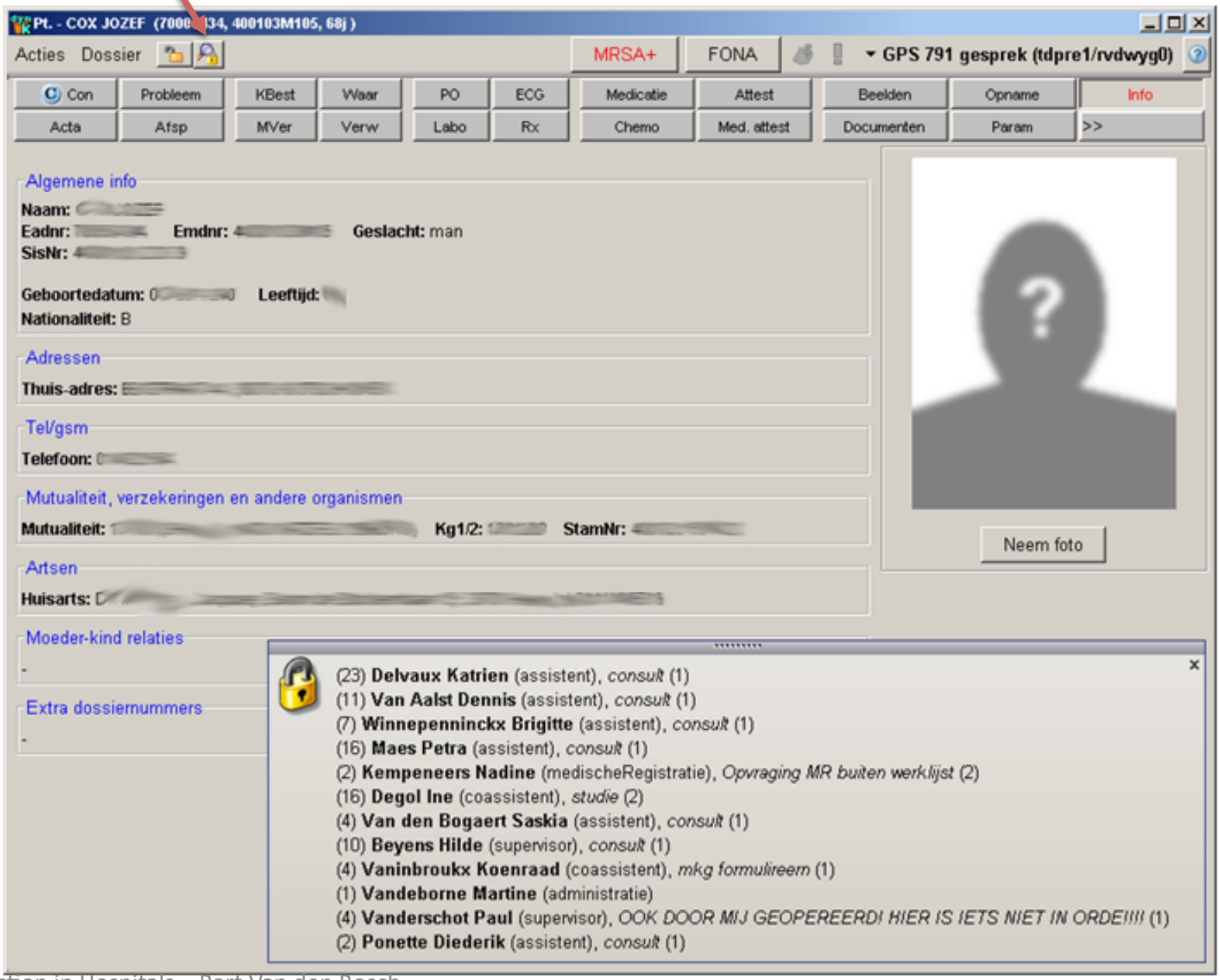
Toon alles (19)
- Billet Bart (2)
- De Bolle Lucia (1)
- Geelen Jos (1)
- Misselyn Dominique (7)
- Theunissen Mimi (1)
- Verbruggen Frederic (5)
- Vermeiren Patricia (2)

overruled door	loginnaam	groep	applicatie	datum	type
Vermeiren Patricia	x227212	trial	*	28-01-2000 11:02	externSysteer
Vermeiren Patricia	x227212	trial	*	28-01-2000 11:02	overruled
Misselyn Dominique	dmisse0	supervisor	heelkunde	21-07-2000 10:24	beweging
Misselyn Dominique	dmisse0	supervisor	heelkunde	21-07-2000 10:24	overruled
Misselyn Dominique	dmisse0	supervisor	heelkunde	21-07-2000 10:24	overruled
Misselyn Dominique	dmisse0	supervisor	heelkunde	21-07-2000 10:24	overruled
Misselyn Dominique	dmisse0	supervisor	heelkunde	21-07-2000 10:25	overruled
Misselyn Dominique	dmisse0	supervisor	heelkunde	21-07-2000 10:26	overruled
Misselyn Dominique	dmisse0	supervisor	heelkunde	21-07-2000 10:26	overruled
De Bolle Lucia	ldboll0	supervisor	anesthesiologie	10-11-2000 08:43	logging
Theunissen Mimi	mtheun0	verpleging	inwendige	31-05-2001 14:25	logging
Geelen Jos	jgeele1	assistent	anesthesiologie	20-11-2001 15:49	logging
Billet Bart	bbille0	assistent	anesthesiologie	03-01-2002 17:09	beweging
Billet Bart	bbille0	assistent	anesthesiologie	03-01-2002 17:09	overruled
Verbruggen Frederic	x218589	hoofdverpleging	heelkunde	28-03-2002 09:18	externSysteer
Verbruggen Frederic	x218589	hoofdverpleging	heelkunde	28-03-2002 09:18	overruled
Verbruggen Frederic	x218589	hoofdverpleging	heelkunde	28-03-2002 09:19	overruled
Verbruggen Frederic	x218589	hoofdverpleging	heelkunde	28-03-2002 09:21	overruled
Verbruggen Frederic	x218589	hoofdverpleging	heelkunde	28-03-2002 09:52	overruled

Sluit
Vernieuw
Nieuwe lijst
Druk selectie

aantal rijen: 19 / selectie: 0

Clicking this button displays the popup again.



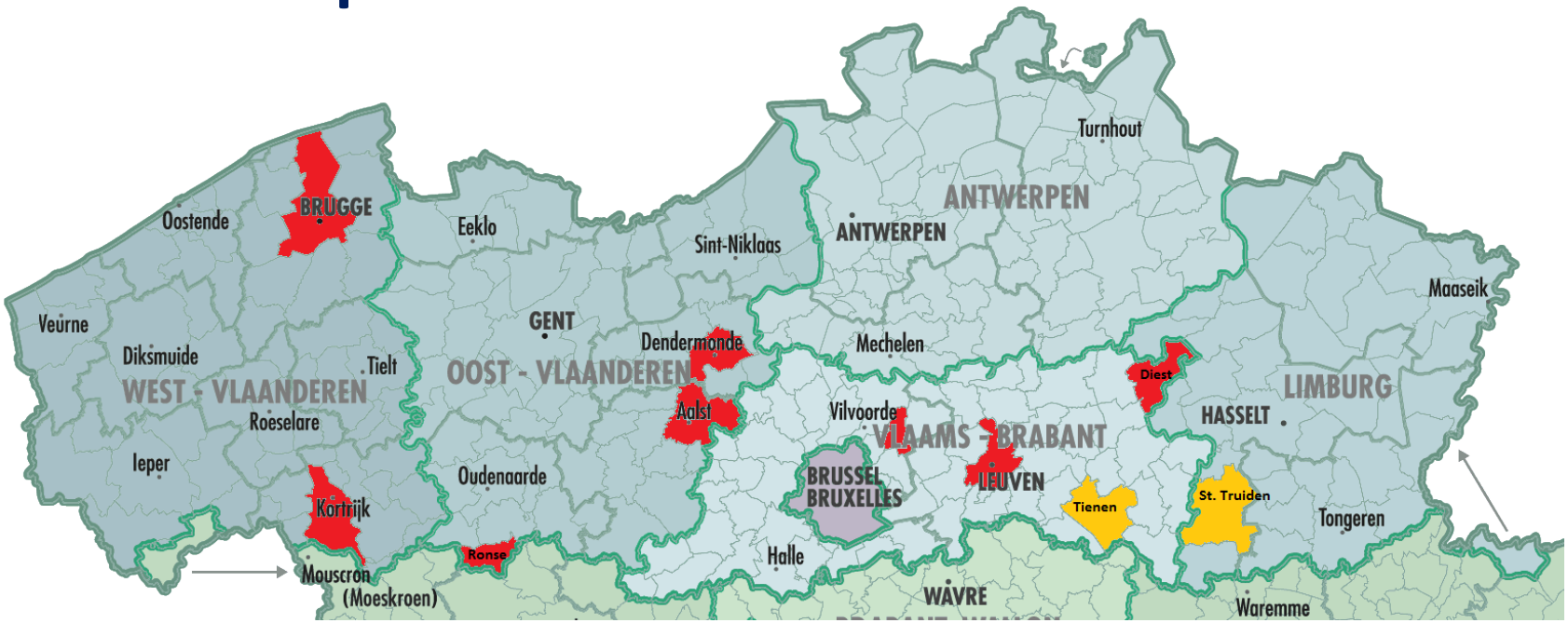
Unique usernames in DB!!!

- Every user action is done on DB with unique userdID
  - Allows to use the logging and audit system of the DBMS itself
- No generic application level userID on DB!!
  - Typical bad habit of 3 tier architecture
  - Invalidates the use of the logging and audit of DBMS
  - Requires rewriting such a system on the middle tier
  - Less secure!

Why need an overrule?

- System might not know yet that you will be involved in the treatment of this patient.
- Access granting can be quite strict: exceptions can be handled by overrule
  - Loose access control → no overrule needed
  - Strict access control → overrule option absolutely necessary
    Remember: no information on paper!
- Structured overrule reasons
  - Code, not free text
  - Allows programmatic checking
    - E.g. if reason is “pre-anesthesia” → Check if patient received anesthesia soon after the overrule

Interhospital overrule



- KWS rolled out in other hospitals
- 2 levels of overrule:
  - intrahospital and
  - interhospital

Security risk prone patients

- All patient accesses are always logged
  - Overrule still necessary
  - Alerts the user “do you really want to do this?”
  - Helps separating “normal” accesses from overruled accesses
- Extreme VIP cases: fake name
  - Dangerous! Might harm patient in an emergency

Procedure checking log

- IT only reacts to a request from mgmt or treating physician
  - Protect privacy of users
- List is first screened by treating physician(s)
- If unlawful access is detected → all overrules to other patients by that user are also screened
  - Gather more evidence that user is not trustworthy

Procedure checking log (2)

- Build up the case firmly
- Hunt down user(s)
- Torture
- Hang ‘em (in public)

A public hanging every now and then does wonders for procedure compliance.

Logs: developers

- System boys set up extra logs for developers (4 eyes principle)
- Changes to applications logs
  - Overrule log
  - Secured patients table
- System logs
  - Login and logout times
  - Tabel create, bcp, truncate, drop, grant for any database object

It works: we actually fired someone based on the 2d level logs.

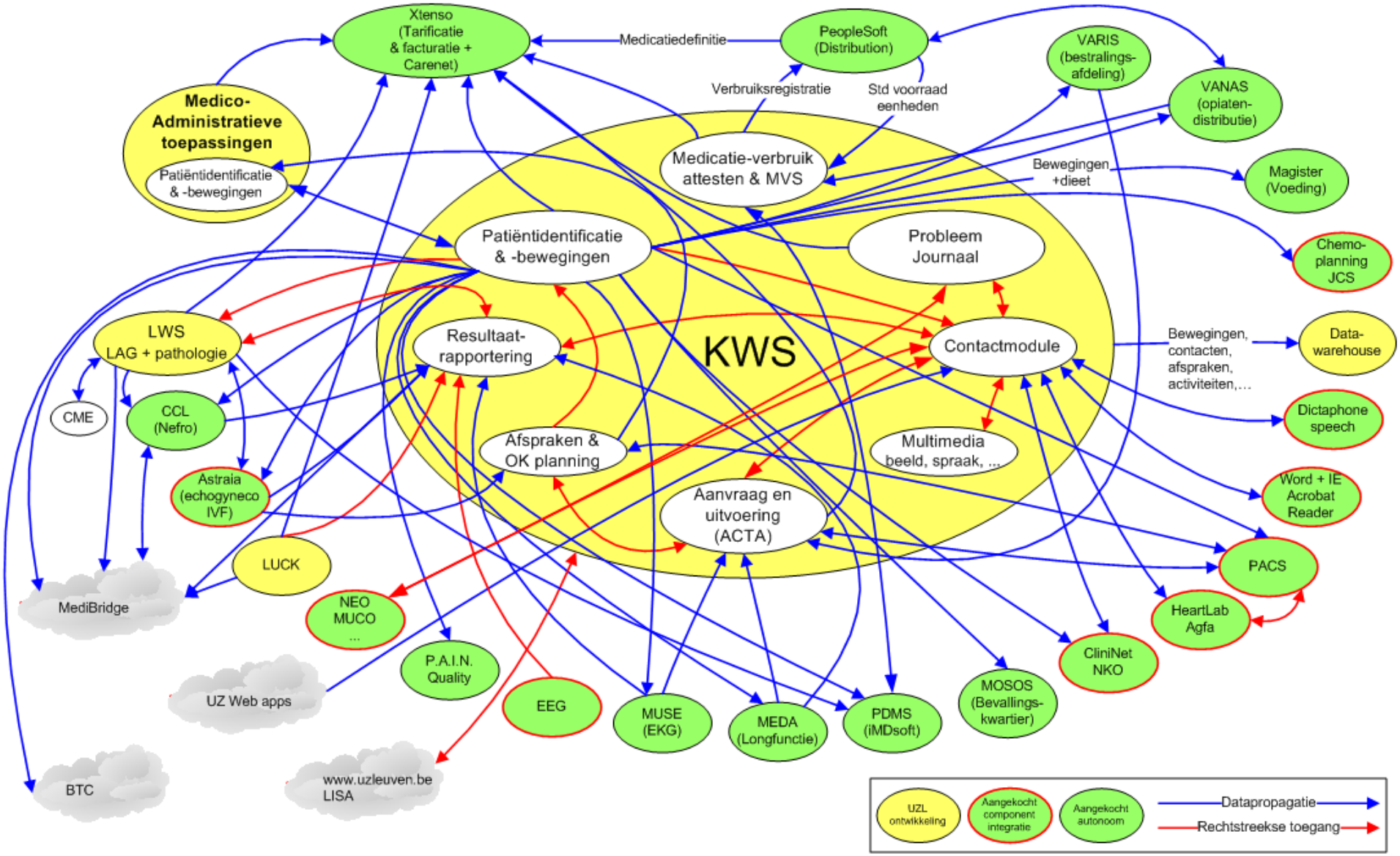
Developers can not remove the traces of their crimes without accessing these logs.

Problem: access control consistency over **ALL** applications

- Any hospital system will have several externally developed ancillary systems
  - Lab, Radiology (PACS), Chemotherapy, PDMS,...
- Data needed to deduce access rights
  - Too voluminous
  - Too volatile (causes many transactions on ancillary system)
- Rules
  - Too complex to implement
  - Too expensive to maintain
- Our (preferred) solutions:
  - **Front end component integration**
  - **Data propagation**

External parties:
- Not up to the task
- Not interested (unless €€€)
- Usually both

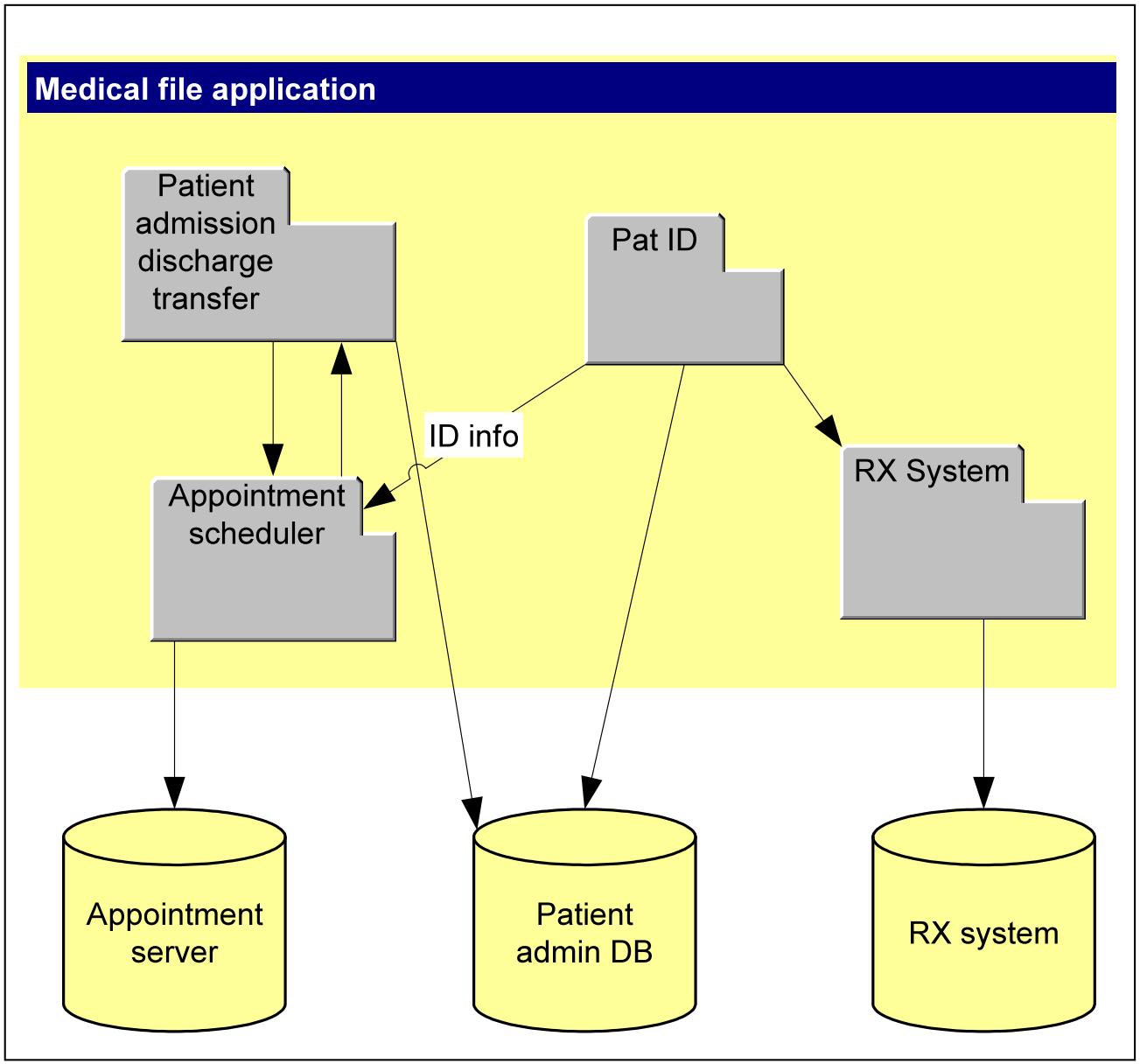
Clinical workstation integration & dataflows



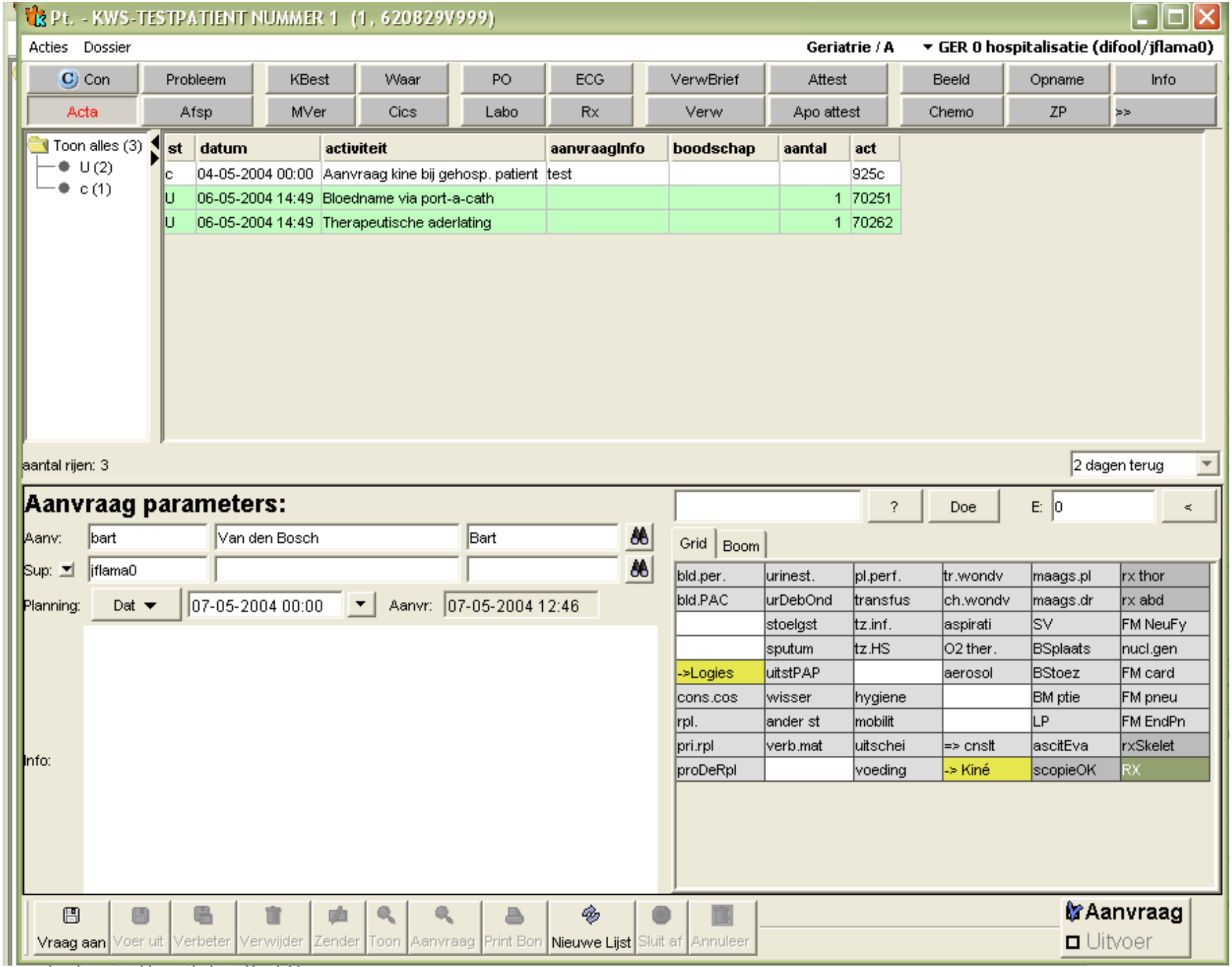
Front end component integration

- External application is embedded as a component within the clinical workstation
- To get to the component you need access on patient level (➔ CWS checks first, then passes control to external component)
- External component should be stripped from all functionalities that allows patient switching

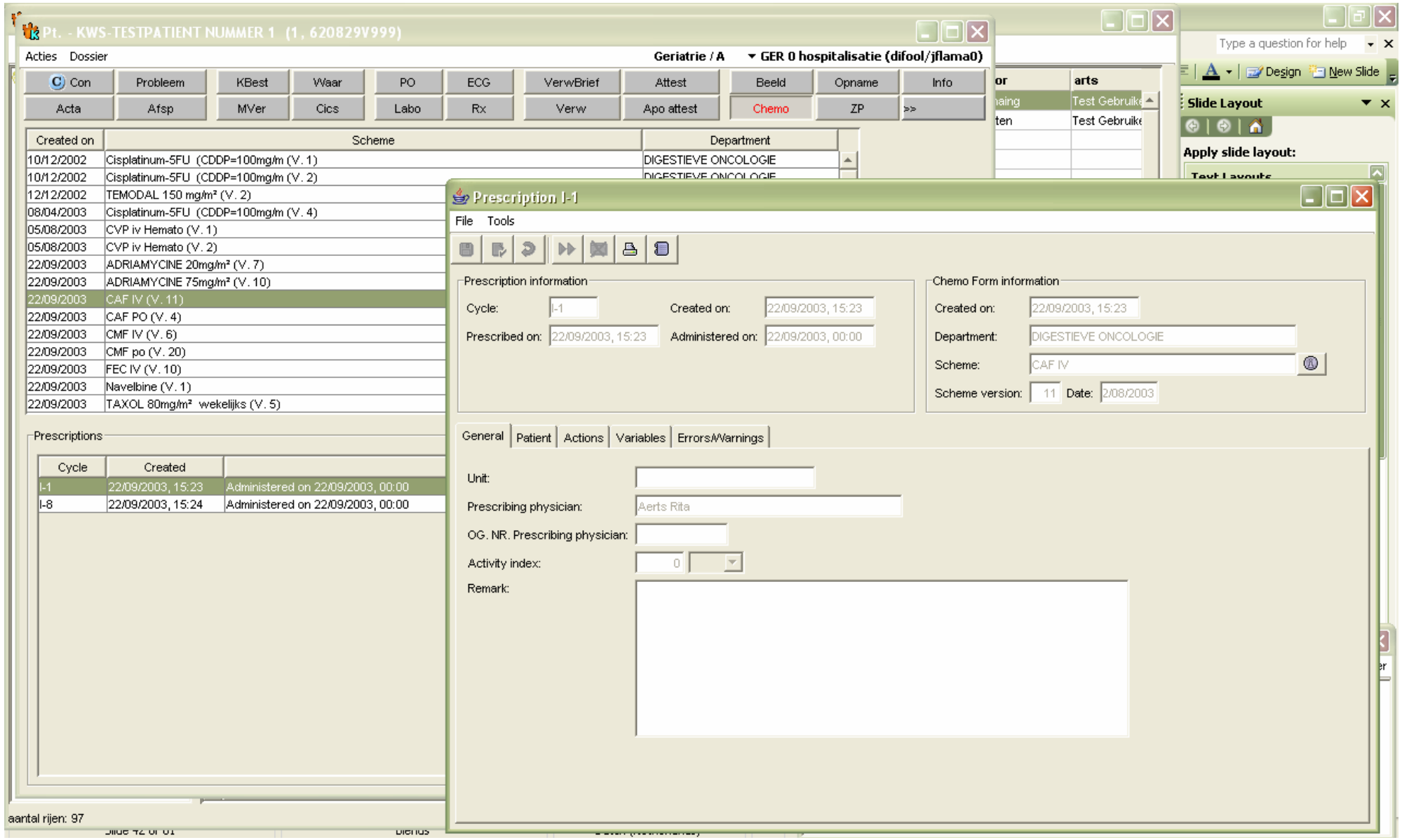
Front end components

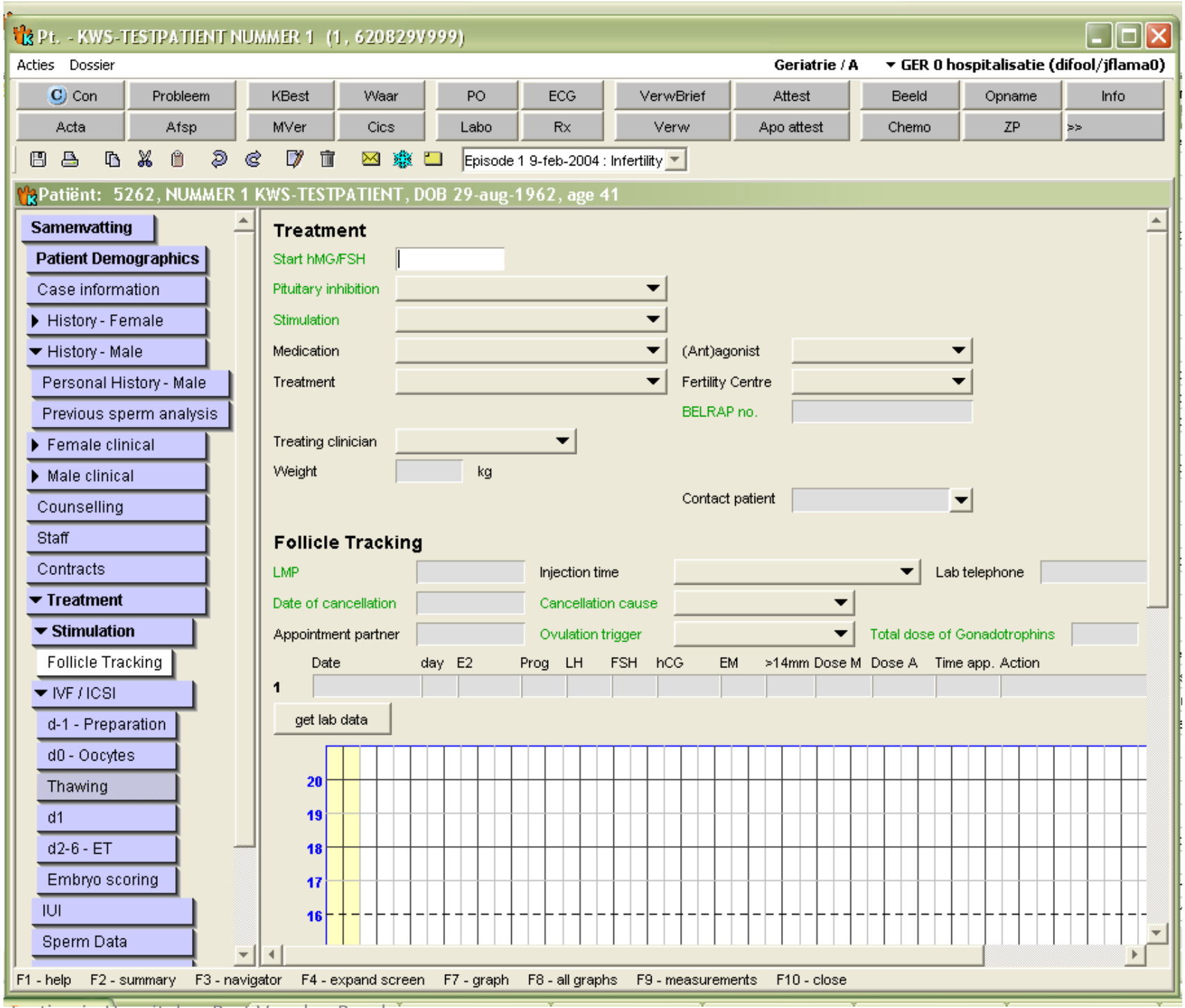


- Encompassing application governs:
  - access control to components
  - acces control to patients
  - interaction between components
- Separate database per component or module
- No function replication necessary: the implemenatation of the logic (the component) is reused


Pt. - KWS-TESTPATIENT NUMMER 1 (1, 620829V999)
Acties Dossier
Geriatrie / A
GER 0 hospitalisatie (difool/jflama0)
Con
Probleem
KBest
Waar
PO
ECG
VerwBrief
Attest
Beeld
Opname
Info
Acta
Afsp
MVer
Cics
Labo
Rx
Verw
Apo attest
Chemo
ZP
>>
Toon alles (3)
U (2)
c (1)
st
datum
activiteit
aanvraagInfo
boodschap
aantal
act
c
04-05-2004 00:00
Aanvraag kine bij gehosp. patient
test
925c
U
06-05-2004 14:49
Bloedname via port-a-cath
1
70251
U
06-05-2004 14:49
Therapeutische aderlating
1
70262
aantal rijen: 3
2 dagen terug
Aanvraag parameters:
Aanv:
bart
Van den Bosch
Bart
Sup:
jflama0
Planning:
Dat
07-05-2004 00:00
Aanvr:
07-05-2004 12:46
Info:
?
Doe
E:
0
<
Grid
Boom
bld.per.
urinest.
pl.perf.
tr.wondv
maags.pl
rx thor
bld.PAC
urDebOnd
transfus
ch.wondv
maags.dr
rx abd
stoelgst
tz.inf.
aspirati
SV
FM NeuFy
sputum
tz.HS
O2 ther.
BSplaats
nucl.gen
->Logies
uitstPAP
aerosol
BStoez
FM card
cons.cos
wisser
hygiene
BM ptie
FM pneu
rpl.
ander st
mobilit
LP
FM EndPn
pri.rpl
verb.mat
uitschei
=> cnslt
ascitEva
rxSkelet
proDeRpl
voeding
-> Kiné
scopieOK
RX
Vraag aan
Voer uit
Verbeter
Verwijder
Zender
Toon
Aanvraag
Print Bon
Nieuwe Lijst
Sluit af
Annuleer
Aanvraag
Uitvoer

Chemotherapy component in Clinical Workstation




Pt. - KWS-TESTPATIENT NUMMER 1 (1, 620829V999)
Acties Dossier
Geriatrie / A
GER 0 hospitalisatie (difool/jflama0)
Con
Probleem
KBest
Waar
PO
ECG
VerwBrief
Attest
Beeld
Opname
Info
Acta
Afsp
MVer
Cics
Labo
Rx
Verw
Apo attest
Chemo
ZP
>>
Episode 1 9-feb-2004 : Infertility
Patiënt: 5262, NUMMER 1 KWS-TESTPATIENT, DOB 29-aug-1962, age 41
Samenvatting
Patient Demographics
Case information
History - Female
History - Male
Personal History - Male
Previous sperm analysis
Female clinical
Male clinical
Counselling
Staff
Contracts
Treatment
Stimulation
Follicle Tracking
IVF / ICSI
d-1 - Preparation
d0 - Oocytes
Thawing
d1
d2-6 - ET
Embryo scoring
IUI
Sperm Data
Treatment
Start hMG/FSH
Pituitary inhibition
Stimulation
Medication
(Ant)agonist
Treatment
Fertility Centre
BELRAP no.
Treating clinician
Weight
kg
Contact patient
Follicle Tracking
LMP
Injection time
Lab telephone
Date of cancellation
Cancellation cause
Appointment partner
Ovulation trigger
Total dose of Gonadotrophins
Date day E2 Prog LH FSH hCG EM >14mm Dose M Dose A Time app. Action
1
get lab data
20
19
18
17
16
F1 - help F2 - summary F3 - navigator F4 - expand screen F7 - graph F8 - all graphs F9 - measurements F10 - close

Data propagation

- Relevant data from ancillary system is propagated to the Clinical Workstation DB.
- No access from outside the dept to the anc system

 Load on local system lower

 Tight access control

 Separate data model to be maintained

 Viewer needed if non text data

Integrity: digital signatures

- Why not use digital signature using the Belgian eID card (BelPIC)?
- User assures himself of the integrity of the data
- IT people can not tamper with the data
- You payed for it, you might as well use it
- BUT....

“Issues”

- You don’t see what you sign.
  - Something is being signed
  - Is what you see on screen what you really sign?
    You have to trust the application
- How many docs do you sign?
  - Application asks PIN code for EVERY signature

This is of paramount importance when using BelPIC: you are personnally (as a citizen, not as an employee) responsible for what you sign.

Wear on BelPIC

- BelPIC estimated life of 25.000 signatures
  - = 5.000 per year (new card every 5 years)
  - = boils down to 23 signatures/day!
- More than adequate for private use, not for professional clinical use!
- Quid costs and temporary impossibility to sign due to defunct BelPIC?

Questions

- Is the safe usage of the BelPIC signature **ergonomically** feasable in a clinical setting?
- Does it legally make sense to use a digital signature in a more ergonomic but less secure way (sacrificing non-repudiation)?
- Can an employee refuse to use his personal BelPIC for professional purposes because of the (however unlikely but) possible misuse where he might be implicated as a person?

Alternatives?

- Separate professional digital signatures from personal ones (separate professional ID card)
- Electronic timestamping
  - Does ensure integrity in time and secures the time when the data was available, but not non-repudiation for the user that inserted the data
  - Can be done without ergonomic cost
  - Time at which a result was in, updated,... often very important.
  - Fraud occurs almost always after the facts: timestamp reveals tampering

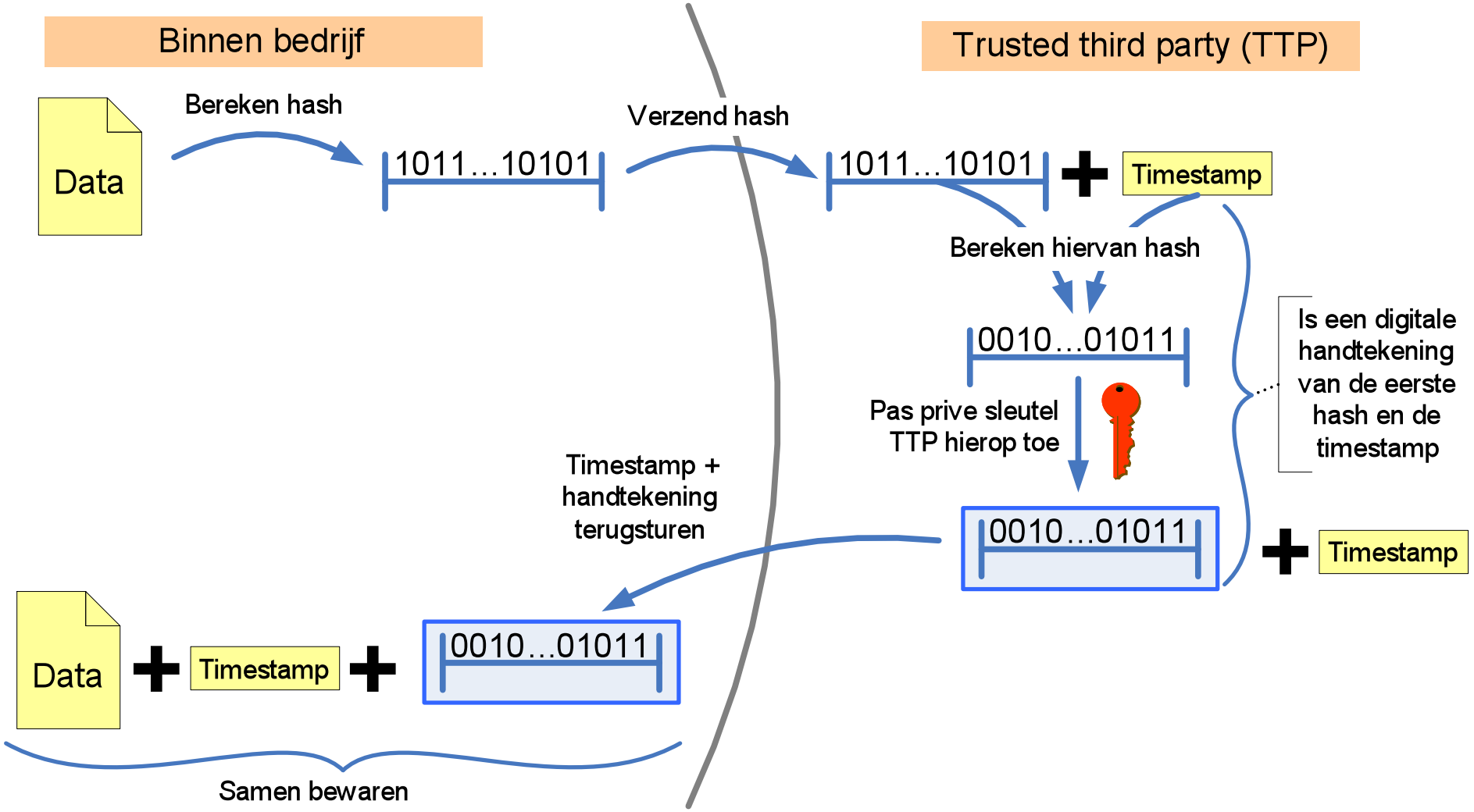
Proposed and developed solution by UZ Leuven

- Combination of Electronic signatures + TTS
- Internal procedure for authentication
  - Passwords, tokens, …
- Prescription are Time stamped by a trusted third party
- Much, much more ergonomical
  - TTS can be done whitout blocking the user
  - Cheap
- We developed the system for the eHealth Platform → officially handed over

Trusted time stamping - TTS

- TTS = way of undeniably determining the point in time when data were entered
  - If data are changed after timestamping ➔ new timestamp necessary
- Most fraude and medicolegal issues center around the exact time when something was known
- Digital signature would not have solved this
- Third party does not see medical data

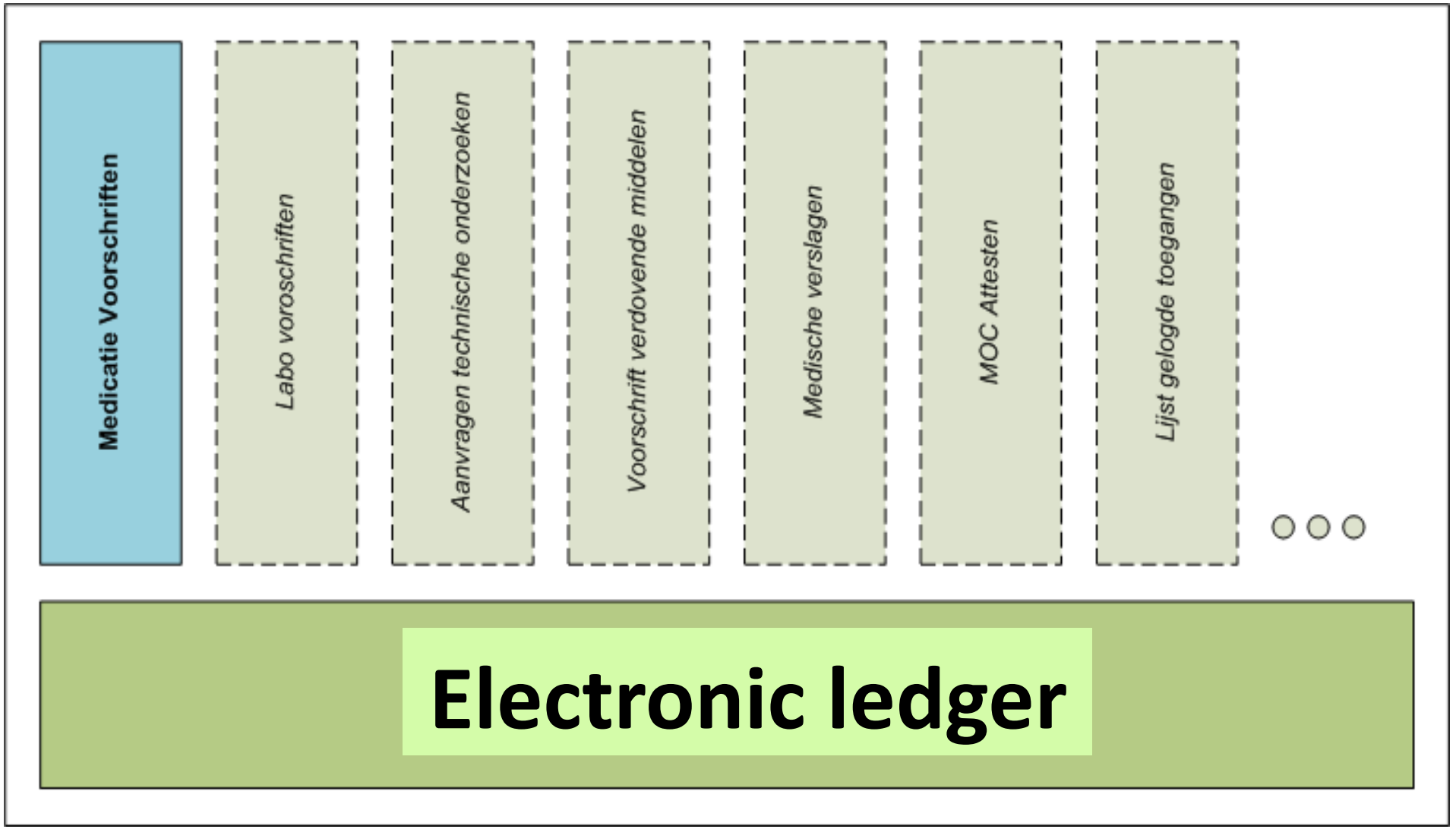
Time stamp by a TTP



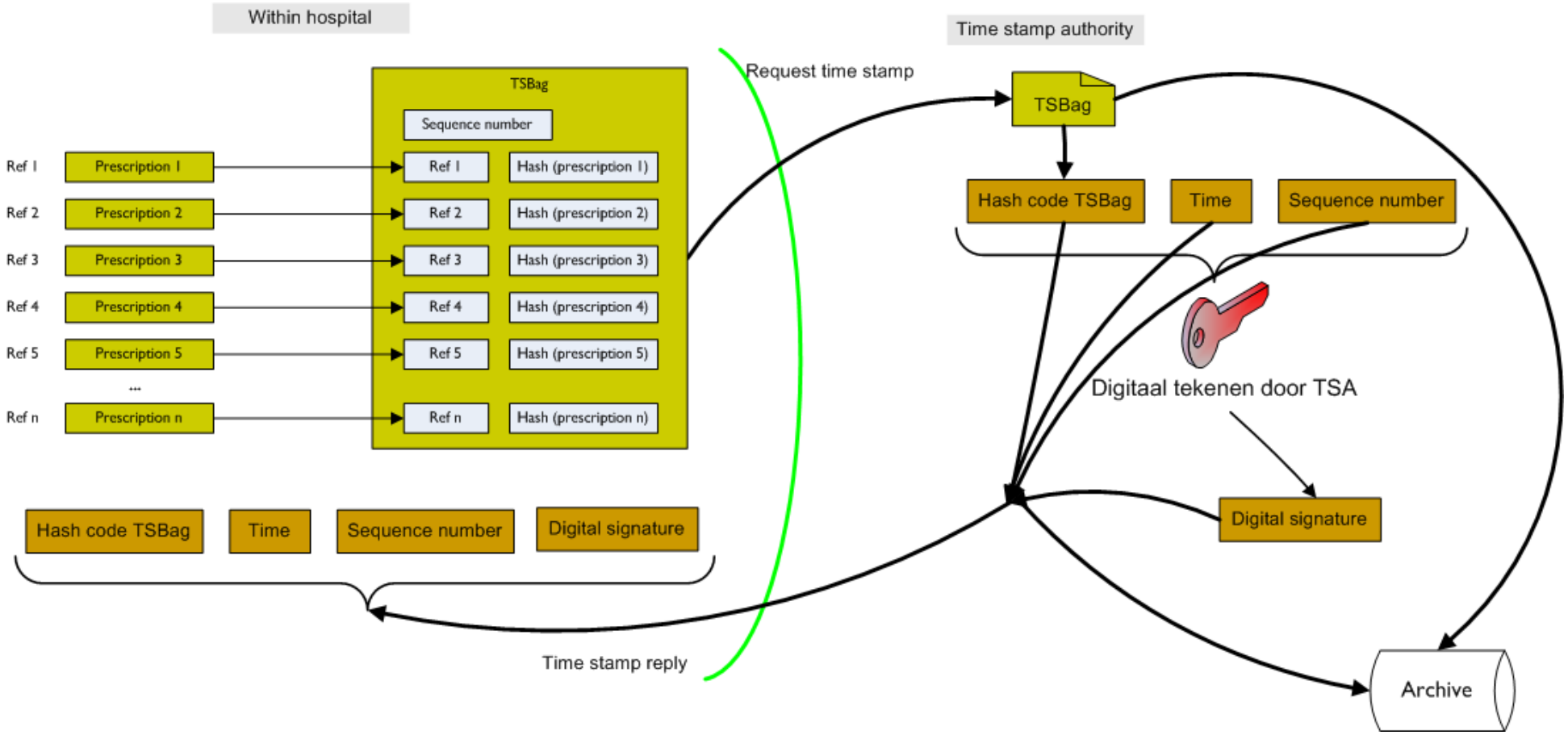
Some challenges

- Every hospital has different systems: ad hoc TTS might be feasable, but checking the timestamps by government officials in different (versions) of systems is unacceptable.
- For performance reasons the individual “journal entries” are collected in a “time stamp bag” (every 5 minutes) and the whole bag is timestamped
- This has some additional security benefits....

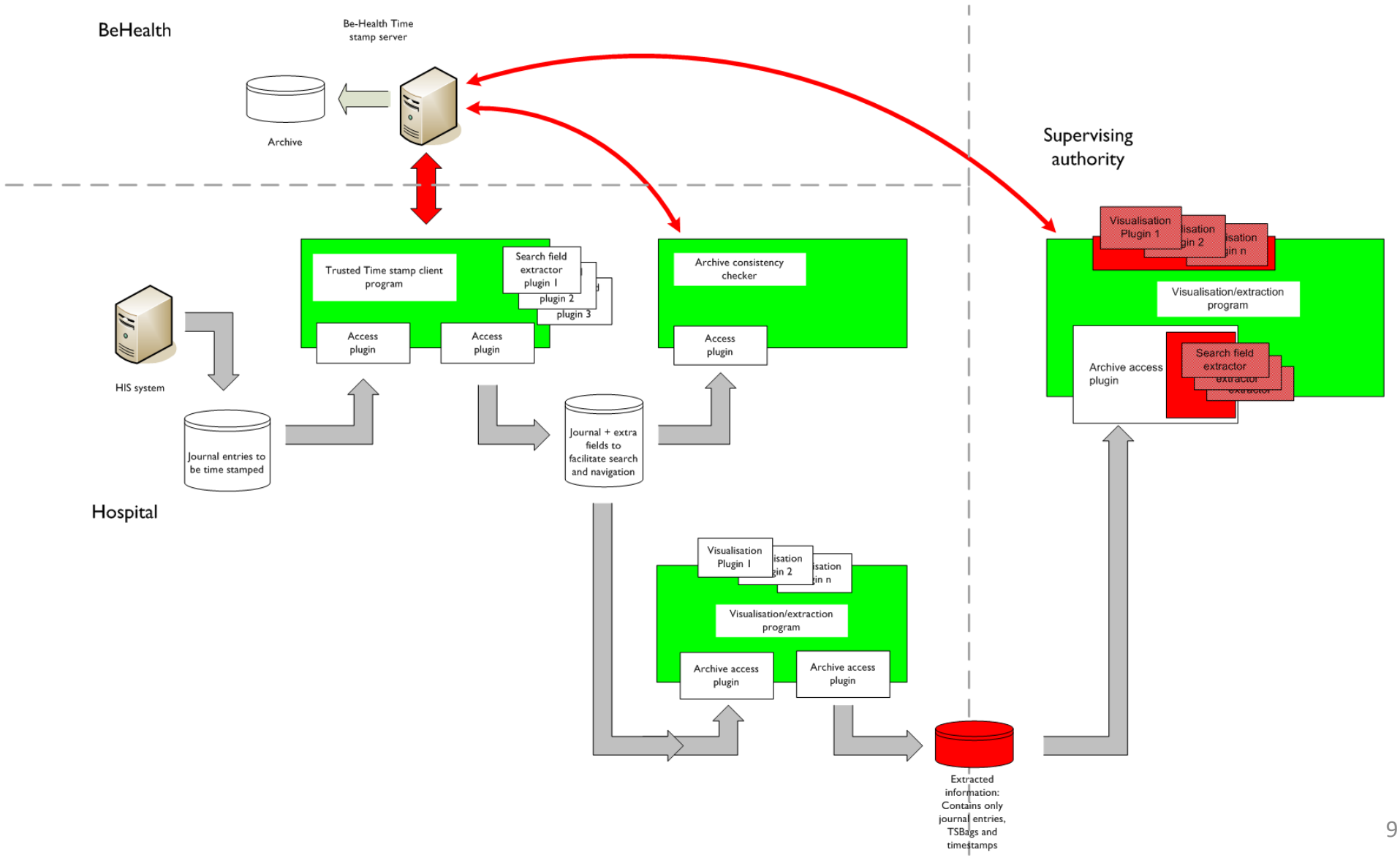
Generic electronic log of timestamps



Journal entries, time stamp bags and time stamps



Overview


BeHealth
Be-Health Time stamp server
Archive
Supervising authority
Visualisation Plugin 1
Visualisation/extraction program
Archive access plugin
Search field extractor
Trusted Time stamp client program
Search field extractor plugin 1
plugin 2
plugin 3
Access plugin
Access plugin
Archive consistency checker
Access plugin
HIS system
Journal entries to be time stamped
Journal + extra fields to facilitate search and navigation
Hospital
Visualisation Plugin 1
Visualisation/extraction program
Archive access plugin
Archive access plugin
Extracted information: Contains only journal entries, TSBags and timestamps

Remember

Security is the reciprocal of convenience

-- Netvision > Ubizen > Cybertrust > Verizon

If you think technology can solve your security problems, then you don't understand the problems and you don't understand the technology.

-- Bruce Schneier (auteur Blowfish)

The user is going to take dancing pigs over security every time.

-- Bruce Schneier (auteur Blowfish)