

SANTAL —

The French Smart

Health Card Application

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SANTAL is an innovative French healthcare project using highly secure multiapplication smart cards for the decentralized storage of patient data. It allows secure communication between patients and healthcare professionals using the portable file capability of the smart card as a secure communication vehicle. This produces a simpler and more comprehensive exchange of healthcare information and simplified administrative procedures.

The SANTAL patient's card contains administrative patient's data (identity, insurance data, entitlements), a portable file with patient's medical data (history, specialist doctor's names, stay in hospital), a portable file with biological data (blood analysis) and pharmacy data (current treatment, prescription, delivery).

Selective access to the patient's card data is controlled by PIN protected SANTAL professional cards, used by healthcare professionals (doctors, nurses, pharmacists, analysts) and administrative personnel.

Special care has been taken to link the SANTAL cards to the French national healthcare system.

This article summarizes the general architecture of the system and reports on the SANTAL trial in the St. Nazaire area (near Nantes) that started in June 1995. This trial uses several thousand patient and professional cards of the type SOLAIC Sx.

SHORT HISTORY OF SANTAL

The SANTAL organization was founded in 1987 to carry out an ambitious pilot project in the French region of Saint-Nazaire. This non-profitmaking organization has its legal headquarters at the St. Nazaire public hospital and its structures unite, with a remarkable degree of cooperation, different categories of institutions and health professionals: Four public hospitals, four private hospitals, eleven laboratories, fifty general practitioners and specialists, and, latterly, pharmacies and nurses, too.

During its development from 1988 to 1993 the SANTAL operation was prepared and run on the orders of the Ministry of Health (hospital direction) and profited from the financial support of the State and different institutions: CIIBA, Social Affairs, CNAMTS (Caisse Nationale d'Assurance Maladie des Travailleurs Salariés), local communities and public hospitals. A pilot committee consisting of financiers and experimenters defined the project orientation and invested in its evaluation.

The first trial phase was successful (37,000 cards issued between 1988 and 1992), but exposed limitations and a number of further requirements. The project committee then assessed the objectives of a second three-year phase, from 1993 to 1995, with a budget of 18 million francs mainly based on public credits. A protocol binding the State to SANTAL was

signed in October 1992 specifying the axes of orientation of the programme "SANTAL.2".

This continuation of the first phase aims at defining and making valid nationwide the medical content of the professional portable file and at favoring the integration of the card into professional health practices. It also intends to integrate administrative functions, especially in the hospital area (admission procedures), paying attention to the convergence with the project SESAM-VITALE. A technical partnership agreement was signed by CNAMTS and SANTAL in August 1992, and the decision to financially support SANTAL was made by CNAMTS in September 1993.

The development of SANTAL requires the installation of efficient tools adapted to the demands of health professionals and based on state-of-the-art technology (systems engineering, cards, readers etc.). To realize this, SANTAL has established a close partnership with Solaic, provider of smart cards and software and Dassault, provider of terminals. The intention is the definition, development and deployment of healthcare products suitable for widespread distribution.

Two distinguished healthcare professionals have launched the SANTAL project and devoted their energies to its successful completion - Mr. P. Cirre and Dr. Leroux. Without their enthusiasm, dedication and expertise this complex project could have hardly succeeded.

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THE FIRST TRIAL

The period between 1988 and 1992 served as an initial introduction and sensitization phase which highlighted specific advantages and technological limitations. Based on the development of the project the preparation of a new stage was launched in 1993 on the request of the SANTAL Orientation Committee and the Ministry of Social Affairs.

The main lessons learnt from the first phase of SANTAL are as follows.

The introduction of the health card was successful, but took much longer than planned, and the real integration of this communication tool in the health professionals' practice has still to be completed. In five years, 38,000 cards were issued, and the population in the Saint-Nazaire region has decided in favor of the idea of an individual health card without raising concerns about privacy rights and the issue of medical secrecy.

The administrative use is well defined and constitutes a potential source of productivity profit and of simplification of patient formalities if certain technical and organizational aspects (especially the updating of rights) are optimized.

The medical application has gained great support from doctors, especially the concept of the emergency card, containing essential data for emergencies. The card's medical content does not require any profound modifications. On the other hand, health professionals seemed reluctant to assume their share of additional work for collecting data and transferring data onto the patients' cards. General practitioners showed more interest in the card than specialists and doctors in hospitals and private practices. In hospitals the SANTAL card was found to be particularly useful for emergency doctors and anaesthetists.

Generally speaking, the card system used in an autonomous way on an isolated terminal was of limited interest. Rather, it is essential to provide systematic interfaces to the local healthcare information systems, which are mostly microcomputer based. The Minitel proved inadequate for allowing data exchanges between the information systems and the cards.

It seemed sensible to increase the number of cards in circulation in order to intensify the usage rate. Nevertheless, hospitals creating cards on request has not proven adequate to intensify card diffusion.

Technically the card system proved reliable with the use of memory chip cards and readers. Nevertheless, a technological leap forward, i.e. the introduction of more efficient, state of the art products (microprocessor cards, sophisticated readers, well engineered modular software) seems indispensable to improve functionality, security, performance and ergonomics.

THE CURRENT TRIAL

Based on the requirements expressed by users, the SANTAL group formulated its objectives for the second phase. Different studies were carried out in 1993, leading to new technical and functional specifications as well as to the development of the card's medical content for the second project phase from 1994 to 1995. A first financial agreement between SANTAL and the Ministry of Social Affairs was signed in November 1992, and a second agreement was established with CNAMTS in October 1993.

The second phase of SANTAL was launched in June 1995. It was scheduled to take place, parallel to the first phase, in the geographical framework of the health sector of Saint-Nazaire and special care was taken to respect healthcare principles.

The strategic objectives of the second phase are as follows:

- To pursue and intensify the card's distribution while still concentrating on the Saint-Nazaire region, from 38,000 cards in early 1993 to at least 60,000 cards at the end of 1995 (equivalent to a quarter of the health sector's population)
- To drive the integration of the card in the hospitals and private practices by optimizing the organizational and technical aspects of the SANTAL facilities to guarantee easier use
- To deepen the medical specialty of SANTAL and to install a "medical information wing" suitable to be recognized nationwide

- To re-center SANTAL on the practice of medicine in the town (general practitioners and specialists) with a better adapted application which integrates prescriptions into the card and takes into account requirements concerning computer workplaces to increase card usage by these kinds of doctors
- To diversify the categories of professionals using the health card of SANTAL by enlarging the user group to pharmacists and nurses
- To develop strong links with the SESAM-VITALE national health insurance system, especially where rights administration is concerned
- To guarantee the integration of SANTAL into the information systems of public and private hospitals via interfaces with local applications
- To contribute to the elaboration of a product that can be generalized and distributed in partnership with industry
- To participate actively in European cooperation programs

The objectives of the second phase of the SANTAL project determine working items to be developed in a three year action programme. These are:

- To choose a modular and evolutionary logical architecture independent of card technology (with the technical help of Solaic)
- To improve the productivity of the development tools as well as the user-friendliness of the applications in the DOS and UNIX environment
- To drive the development of the card, from the relatively simple memory card used in the first phase to a state of the art multiple purpose smart card, of the type Solaic Sx with a memory of 24 KB
- To move to a modern terminal technology, using the LCM 322 produced by Dassault A.T. which lets the card readers use an intelligent terminal programmable in a high level computer language

The reader is integrated in either of the two SANTAL workstation types. The first one (temporary, in anticipation of computerization of the doctors) is a stand-alone terminal, controlling a printer to output the card content. The second one will be connected to a microcomputer (for computerized doctors and hospitals).

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These developments should lead to the introduction of a system which is, for the time being, different from that used by VITALE, although compatibility is foreseen as a long term objective.

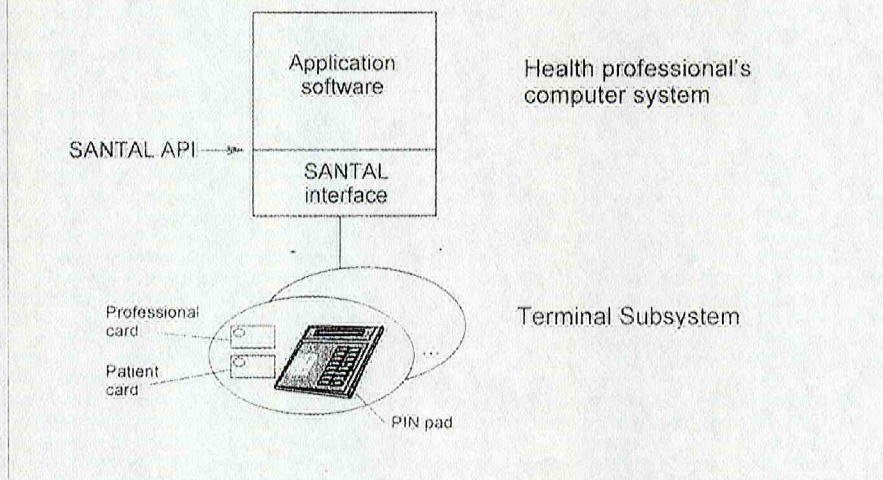
THE CONCEPT OF SANTAL

The aim of the SANTAL project is to contribute to the development of the professional healthcare communication system so as to favor the emergence of a more integrated and thus more efficient information system, common for the different categories of professionals. This is based on the use of a smart card allowing the circulation of medical and administrative data at a very high security level and respecting confidentiality rules and the deontological rules of practical medicine.

This is achieved by placing the patient's medical data on a personal portable file residing on the microprocessor chip of the SANTAL patient's card, thus creating a decentralized, portable medical database that allows better communication between patients and healthcare professionals and speeds up and simplifies administrative procedures. Access to this portable file is highly secure and controllable using SANTAL professional cards specific for doctors, biologists, chemists and administrative personnel. This is exemplified in figure 1.

Access to the data on the patient's card complies with French regulations and laws.

Figure 2: SANTAL overall architecture



OVERALL ARCHITECTURE

The SANTAL overall architecture comprises cards, terminals and a software interface between diverse applications running in health professionals' computer systems and the terminals as described in figure 2.

Communication and interaction between computer system and terminals is kept to the minimum needed.

THE SANTAL CARD TECHNOLOGY

The card technology selected for SANTAL is based on microprocessor chips, allowing structuring of data in secured compartments as well as off-line verification of the cardholder using a PIN (especially relevant for the professional card). The logical

partitioning of the data in the patient's card is shown in figure 3 on page 24.

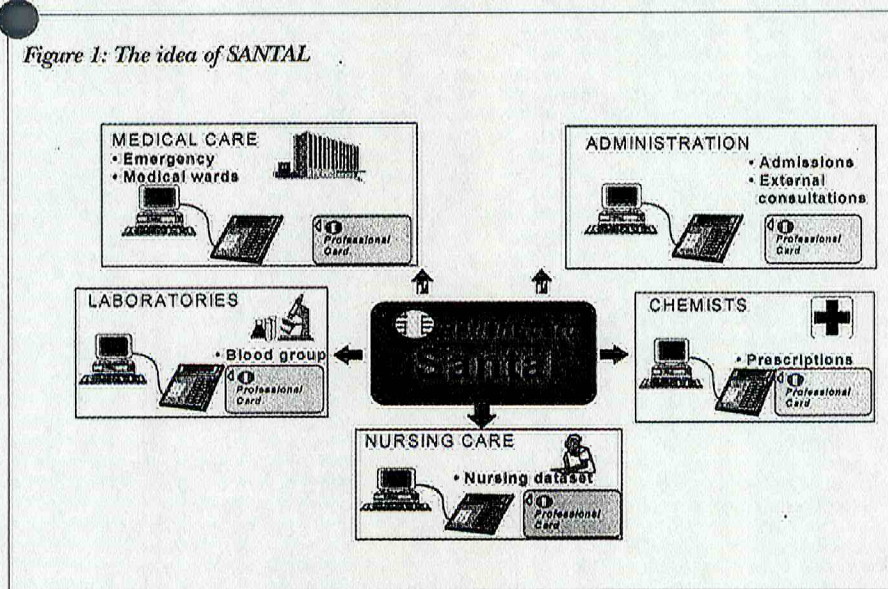
THE SANTAL IMPLEMENTATION ON SOLAIC'S SX MULTIPURPOSE CARD

The data on the patient's card stored in EEPROM is structured in directories and files in order to achieve optimal data compaction under the 3 KB EEPROM address space constraint of the chip used.

The data written on the card uses a five/six bit code to represent alphabetic/ alphanumeric characters, thus achieving a further degree of compaction. A special software layer between the card terminal and the application translates the eight bit ASCII characters to the internal five/six bit representation. Given the space limitations, the number of entries and hence the size of medical history, stays in hospital and medical drugs prescribed and delivered have been limited. The medical records entered by doctors in the medical history in the EF file use a free format. The stays in the hospital are described by means of free form fields currently using an external format including:

- Establishment
- Discipline
- Entry date
- Doctor attending
- Diagnosis
- Type of operation
- Nature of intervention
- Signature of doctor

Figure 1: The idea of SANTAL



The diagnosis above is not coded but entered in a free form within a text box of five lines. The nature of the intervention can be specified in one line. One line consists of 78 ASCII characters.

Drug prescriptions are placed on the SANTAL patient's card in the EF drugs & prescriptions. The current layout of the EF allows for two prescriptions with specifications of 22 drugs. Prescription data includes:

- AMM code (a seven digit code used in France to describe products)
- Posology (times per day/number of days)
- Date of prescription
- Signature of doctor

Delivery data includes:

- Quantity to deliver
- Quantity delivered
- CIP code
- Substitution of medication

When entering a new prescription, the doctor decides which of the existing prescription data is going to be overwritten.

THE SANTAL PROFESSIONAL CARD

The purpose of the SANTAL professional card is to gain access to the data required on the patient's card, in order to read or read and modify it, according to the needs and rights of each professional. For this purpose, professionals are divided into categories:

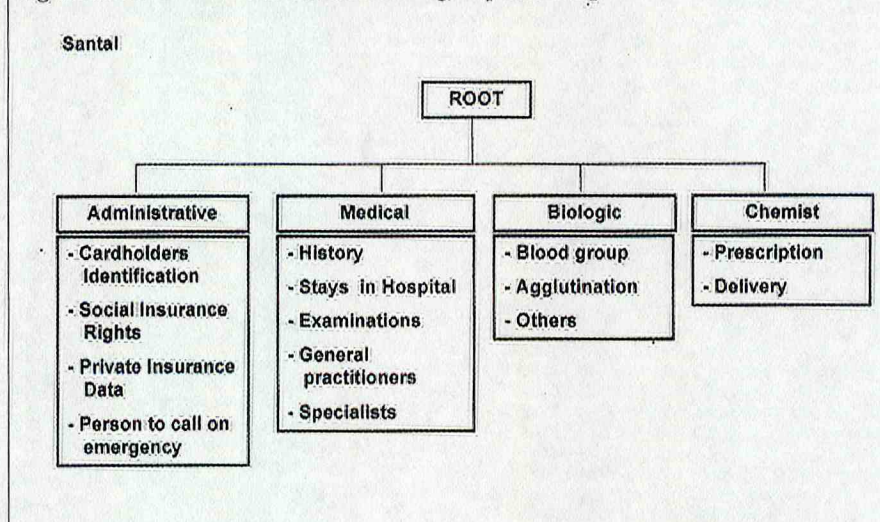
- Administrative
- Medical
- Biologist
- Chemist

Taking into account the specific technical, functional and legal environments within each of the categories above, different profiles are specified, as summarized in figure 4.

THE SANTAL TERMINALS

The architecture of the SANTAL terminal subsystem takes into account the need to integrate cards and terminals within many

Figure 3: SANTAL Patient's card data and logical partitioning



different environments and the requirement to do so with maximum flexibility and minimum overhead and cost, granting security and availability. This is not a straightforward issue. The standard configuration is shown in figure 5 on page 26.

SECURITY

Access to the patient's card is only possible on the simultaneous presentation of a professional card. Verification of the professional's identity takes place by the cardholder entering his PIN on the terminal's pin pad. This validates the professional and the professional card used within the terminal. Access to the

patient's data takes place after mutual authentication between professional and patient's card as well as presentation of access entitlements to the patient's card for each data access. Security operations are performed by the terminal. None of the keys used in the security procedures are stored within the terminal; all keys involved in the security exchanges reside on the professional and patient's cards and do not circulate in the clear within the terminal but are enciphered. All security exchanges remain within the terminal subsystem, so there is no exchange of security data between terminal and the professional's computer system.

Figure 4: Patient's card access rights to medical applications

Item	ADMIN	BIOLOG	G.P.	SPEC.	NURSE	CHEM	STUD
Medical History	F	R	W	W	R	T	R
Doctors (GP, specialists)	F	R	W	W	R	T	R
Stays in hospital	F	R	R	W	R	T	R
Examinations	F	R	W	E	R	T	R

Rights : Write, Erase, Read, Temp. right, Forbidden

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TERMINAL CAPABILITY

The terminal's software is specifically customized to handle the security exchanges between professional and patient's card, as explained above. Furthermore, it takes care of the high level communication with the professional's computer system and handles the guidance of the user, prompting for insertion of cards, entering of PINs and catering for exceptional situations.

Often terminal software is written in assembler or some kind of macro language or interpreter. This approach was considered unsuitable for the SANTAL architecture, so a C programmable terminal with a powerful processor, plenty of memory, two card reader slots and a secure PIN pad was selected (Dassault LCM 322) and programmed by Solaic.

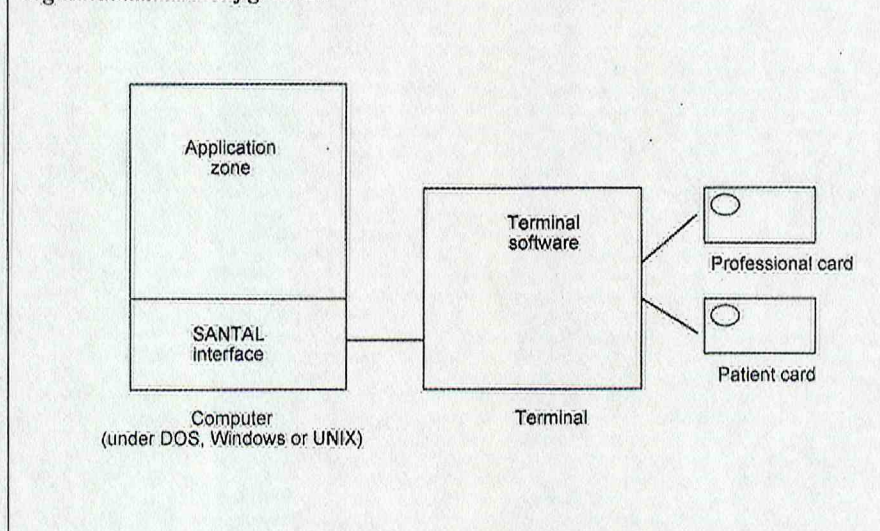
RESULTS SO FAR

As of July 1995, roughly 500 cards had been distributed on a voluntary basis to patients visiting or staying at the St. Nazaire Hospital and all 5,000 inhabitants of the small city of Port Château near St. Nazaire had received SANTAL cards. In Port Château all ten doctors and six pharmacies are participating in the trial. No major technical problems have happened so far and acceptance is good. The general feeling of patients and doctors is that the card is useful for simplifying administrative chores (such as hospital registration) and valuable for follow-up of operations. Furthermore, placing prescriptions on the cards helps avoid paperwork at the pharmacies and provides a good prescription tracking mechanism for doctors. Linkage to the national health service works, too.

EXTENSIONS AND FUTURE PERSPECTIVES

The SANTAL patient's card has real value in emergencies, due to the medical information it contains. Nevertheless, there is no specific summary of medical history for emergencies. Furthermore, a SANTAL cardholder might not just experience an emergency within the SANTAL experimentation area. Therefore it would be beneficial to define a common set of

Figure 5: Standard configuration



emergency data that could be read and understood in different sites within a country or Europe. For this purpose a standardization group is currently working on the definition and interoperability of emergency data (Cardlink) and the European cities of Saint Nazaire, Dublin, Rome, Mailand and Valencia are participating in the Cardlink project.

In some of these cities health cards are being trialled. Within the Cardlink project, the emergency data sets will be integrated into the data structures defined within the cards in order to ensure interoperability.

Concerning SANTAL, the emergency data will be integrated within the existing card modifying the file layout discussed so far. The enhanced SANTAL emergency card may be called 'SANTAL/Cardlink'.

The panorama of health cards in France has not settled down yet; many technical, administrative, economical, political and legal issues remain. On top of that, data privacy and psychological aspects affect the decision process, slowing it down considerably. In this context, SANTAL is to be understood as a serious trial of real health cards in a representative environment. There are other cards related to healthcare in France, like the VITAL card, used for administrative purposes or the CPS card (carte professionnelle de santé) the functionality of which should roughly correspond to the

functionality of the SANTAL professional card. At the time of developing the second phase of SANTAL the CPS card was still being discussed and specified; deployment and use of the CPS in France is scheduled by the end of 1995. The decision to define and produce a specific SANTAL professional card was taken so that the SANTAL trial could start in the first half of 1995.

After enough experience from the trial has been obtained (after one or two years' real operation) a decision concerning extension of the SANTAL concept to the rest of France could take place. Indeed, the principles and technology could well apply to any modern health-care scheme.

This article has been adapted from a presentation given at the Health Cards '95 conference, Frankfurt/Main 23-26 October 1995.

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