(54) Title: SYSTEM AND RELATED CHIP CARD TYPE PORTABLE STORAGE MEDIUM FOR MANAGING HEALTH DATA

(57) Abstract: The invention concerns a system for managing health data of a plurality of individuals of a population, comprising: - one or more database (3), each one of which stores at least one portion of health and/or administrative data of said individuals; - a plurality of processing apparatuses (1), each located in a corresponding health site, capable to connect with said one or more databases (3) through a communication network (2); and - at least one portable storage medium (4) for each one of said individuals, storing identification data of the individual, said identification data of the individual of said at least one portable storage medium (4) being capable to be read by at least one of said plurality of processing apparatuses (1) for enabling said at least one processing apparatus (1) to refer to and/or update at least one portion of said health and/or administrative data stored in said one or more databases (3). The invention further concerns a portable storage medium (4) and the related electronic reading device.
For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Published:
- with international search report
The present invention concerns a system, and the portable storage medium, preferably a chip card type electronic and/or magnetic card, used by the system, for managing health data, also comprising administrative data of interest for providing health services, that allows a timely reference and a rapid updating of all health data related to each individual of a however large population, ensuring a very high safety and privacy, so as to enable any authorised health operator to know in a controlled manner, for instance, the anamnesis of the patient for assessing in good time possible diagnoses, with a consequent decrease of complications and mortality rate due to delayed diagnoses, the system being simple and inexpensive to make, install, and use.

The present invention further concerns an electronic device for reading said portable storage medium.

It is known that in the field of health services management, at local level, as in a single hospital site, but still more at geographically distributed level, as in a region or over the whole home territory, detailed management of health data of the population benefiting from the same services is of fundamental importance.

In fact, a detailed knowledge of health data, as much updated as possible, which form the patient anamnensis, would allow to assess in good time diagnoses of possible pathologies, to arrange proper prevention campaigns for persons at risk of specific diseases, and to carry out either exact or statistical searches on specific samples of population.

However, the large amount of information to manage has rendered the implementation of an efficient and reliable health data managing system complex and expensive so far.

In fact, the systems developed so far suffer from some drawbacks which have highly limited their applications.

In particular, the existing systems are limited to the management of a very reduced portion of data of extremely limited populations, such as those receiving a specific health service within a health site. For instance, there exist systems allowing the management only of administrative data within a whole hospital site, but which do not manage health data of the services received in one of the divisions of the
same structure; these data are managed by a further different managing system, such as those making use of the HL7 protocol for managing an electronic case history made up within a specific division of the hospital site. This entails a great difficulty in integrating data managed by different systems, which are often not even capable to automatically communicate with each other, with a consequent delay of the availability of the same data, an unavoidable incompleteness of available health data, and an increase of the maintenance costs for these systems, due to the large number of personnel that is to be involved in data entry and updating.

It is therefore an object of the present invention to provide a system for managing health data of a however large population, that allows a timely reference and a rapid updating of all health data, also comprising administrative data of interest for providing health services, related to each individual of a however large population.

It is still an object of the present invention to provide such a system that ensures a very high data safety and privacy.

It is further an object of the present invention to provide such a system that is simple and inexpensive to make, install, and use.

It is specific subject matter of the present invention a system for managing health data of a plurality of individuals of a population, comprising:

- one or more databases, each one of which stores at least one portion of health and/or administrative data of said individuals;
- a plurality of processing apparatuses, each located in a corresponding health site, capable to connect with said one or more databases through a communication network; and
- at least one portable storage medium for each one of said individuals, storing identification data of the individual, said identification data of the individual of said at least one portable storage medium being capable to be read by at least one of said plurality of processing apparatuses for enabling said at least one processing apparatus to refer to and/or update at least one portion of said health and/or administrative data stored in said one or more databases.

Always according to the invention, said portable storage medium may comprise at least one processing unit, preferably a microprocessor.

Still according to the invention, said portable storage medium
may comprise at least one electrically erasable programmable read only memory or EEPROM.

Furthermore according to the invention, said portable storage medium may further store at least one software application and/or further data capable to set up said at least one processing apparatus reading the same for referring to and/or updating said at least one portion of said health and/or administrative data stored in said one or more databases.

Preferably according to the invention, said portable storage medium is a smart card.

Always according to the invention, said portable storage medium may comprise a communication interface according to the USB standard.

Still according to the invention, said portable storage medium may comprise at least one magnetic stripe.

Furthermore according to the invention, at least one of said plurality of processing apparatuses may comprise at least one input/output or I/O interface port capable to receive said at least one portable storage medium so that said at least one processing apparatus reads said identification data of the individual.

Always according to the invention, at least one of said plurality of processing apparatuses may be capable to be connected to an external electronic device for reading said at least one portable storage medium, so that said at least one processing apparatus reads said identification data of the individual.

Still according to the invention, at least one of said plurality of processing apparatuses may be a processing apparatus selected from the group comprising a computer, a hand-held device, and a cellular telephone.

Furthermore according to the invention, said at least one portion of said health and/or administrative data, that is referred to and/or updated by said at least one processing apparatus, may depend on at least one identification code of a health operator operating on said at least one processing apparatus.

Always according to the invention, said at least one identification code of the health operator may be inserted through a user-id/password type input interface, and/or may be preinstalled in said at least one processing apparatus, and/or may be read from a further
portable storage medium.

Still according to the invention, said health and/or administrative data of said individuals may comprise:

- personal data of said individuals, and/or

- diagnosis and/or analysis and/or report clinical data concerning said individuals, and/or

- data related to reservations and/or health services benefited by said individuals, and/or

- data related to sensitivities or intolerance of said individuals to chemical and/or biological substances, and/or

- data related to therapeutic prescriptions of said individuals, and/or

- data related to an expression of will to be an organ donor.

Furthermore according to the invention, one or more of said individuals whose health and/or administrative data are stored in said one or more databases may be health operators, and the related health and/or administrative data of said health operators may comprise their personal data.

Always according to the invention, at least one of said one or more databases may store at least one portion of health and/or administrative data of said individuals in a data structure of relational type.

Still according to the invention, at least one of said one or more databases may store at least one portion of health and/or administrative data of said individuals in a data structure of object type.

Always according to the invention, said one or more databases may be geographically distributed.

Still according to the invention, said at least one processing apparatus may be capable to refer to and/or update at least one portion of said health and/or administrative data stored in said one or more databases through a browser graphical interface.

Furthermore according to the invention, said health and/or administrative data of said individuals may be capable to be updated through a connection according to the HL7 protocol with an external system storing updating data comprising electronic case histories.

Always according to the invention, at least one portion of said health and/or administrative data of said individuals may be transmitted over the communication network in encrypted format.
Furthermore according to the invention, at least two of said plurality of processing apparatuses may be capable to connect to each other through said communication network.

Still according to the invention, said communication network may be at least partially a wireless, preferably satellite and/or cellular telephony, communication network and/or at least partially a wired, preferably land line and/or fibre-optics telephony, communication network.

Furthermore according to the invention, said communication network may comprise the Internet network.

Always according to the invention, said health sites may comprise at least one surgery, and/or at least one hospital, and/or at least one specialist’s surgery, and/or at least one ambulance, and/or at least one pharmacy, and/or an orthopaedic workshop, and/or at least one medical device provider.

It is still subject matter of the present invention a portable storage medium, characterised in that it stores identification data of an individual capable to be read by at least one processing apparatus for enabling this one to refer to and/or update at least one portion of health and/or administrative data stored in one or more databases, and in that it is capable to be used by the previously described system for managing health data of a plurality of individuals of a population.

It is further subject matter of the present invention an electronic reading device, capable to be connected to at least one processing apparatus, characterised in that it is capable to read at least one portable storage medium as just described, and in that it is capable to be used by the previously described system for managing health data of a plurality of individuals of a population.

The present invention will now be described, by way of illustration and not by way of limitation, according to its preferred embodiments, by particularly referring to the sole Figure of the enclosed drawings, in which it is schematically shown a block diagram representing a preferred embodiment of the system according to the invention.

The system according to the invention comprises, for each health site, at least one processing apparatus 1, preferably a computer or a hand-held device (such a PDA – Personal Digital Assistant), or even a suitably configured mobile telephone, by means of which a health operator accesses, through a communication network 2, the health data of a user
stored in a database 3. The access is authorised through at least one portable storage medium 4, read by the processing apparatus 1, that stores an identification code of the user whose data must be referred to and/or updated by the health operator. Preferably, also the health operators are provided with their own identification code, so as to allow a discrimination of the data which different operators may see and/or update and a distinction among the operations which different health operators may make on the same data (only reference, only updating, or both).

In particular, in the Figure a number of processing apparatuses are shown comprising, by way of example and not by way of limitation:

- a processing apparatus 1A located in a surgery;
- a processing apparatus 1B located in a hospital;
- a processing apparatus 1C located in a first aid station;
- a processing apparatus 1D located in a specialist's surgery;
- a processing apparatus 1E located on an ambulance, which communicates with the network 2 by means of a wireless connection, for instance with cellular telephony, achieved through a receiving-transmitting antenna 5 connected to the processing apparatus 1E communicating with a station 6 connected to the network 2;

- a processing apparatus 1F located in a pharmacy;
- a processing apparatus 1G located in an orthopaedic workshop;
- a processing apparatus 1H located in a medical device provider.

It is evident that, as said, thanks to the identification code of the health operators, these will be capable to refer to and/or update only information (either as a whole or a subset thereof) which is pertinent to their own job. For instance, in case of an hospital administrative operator, he will be capable, through the processing apparatus 1B, to read some administrative data (as user's personal data, reservations and already made visits, paid expenses) and to update other ones (as new reservations and visits to make); in case of a doctor on an ambulance, he will be capable to refer to medical data forming user's anamnesis; in case of a pharmacist, he will be capable to refer to some medical data, as sensitivities or intolerance to specific substances, possible previous therapeutic prescriptions, and still to give drugs and medicines previously prescribed by a doctor (recorded in the database 3, and possibly also in
the portable medium 4) and further to record (in the database 3 and possibly also in the portable medium 4) the given drugs and medicines, thus implementing a sort of electronic prescription system. In the latter case, by way of example, the doctor could record (in the database 3 and possibly also in the portable medium 4) a prescription, the user could go to the pharmacy and give the portable medium 4 to the pharmacist, who read, through the processing apparatus 1F, such prescription highlighting the drug cost and the possible contribution (for instance a "ticket") that the user must pay; moreover, the pharmacist may further record (in the database 3 and possibly also in the portable medium 4) the occurred consignment of the drugs to the user. Such a system could be further adopted for having specialists' visits or for making lab analysis in hospital sites, whereby the recorded (in the database 3 and possibly also in the portable medium 4) electronic prescription would be read and interpreted by a processing apparatus of the hospital site.

The identification code of the health operators may be inserted through a conventional user-id/password type interface, or it may be pre-installed in the related processing apparatus (possibly confirming the operator identity with a standard procedure of request of a password, possibly accompanied by an operator's "user-id"), or it may be stored in a portable storage medium, as a key according to the USB standard or a smart card, similar to the user's medium 4.

Even the user may connect, by means of his/her own processing apparatus 1J, through the network 2 to the database 3, after authorisation through the portable storage medium 4, read by the processing apparatus 1J, and preferably after a further user's identification code allowing him/her only to refer to his/her own data stored in the database 3, and not to update (unless particular information, as for instance the expression of will to be an organ donor).

The communication network 2 may comprise any combination of one or more standard communication networks (for instance even the Internet and/or a dedicated network), implemented through telephone, in particular cellular, connection and/or satellite connection and/or fibre optics connection.

The portable storage medium 4 substantially constitutes the input port towards the database 3 containing the whole anamnesis history of all the individuals of the population since birth and along the whole
space of life. A subset of the health and/or administrative data of the user could be also locally stored on the medium 4.

Preferably, the portable storage medium 4 is a smart card provided with a microprocessor. The inventor has tested an embodiment of the system that makes use of the AT90S2343 chip card from Atmel Corporation. Such medium 4 comprises an electrically erasable programmable read only memory or EEPROM storing, besides the identification code of the user whose information is to be searched in the database 3, also a software application and possible further data allowing to set up the health operator’s processing apparatus 1.

In particular, the connection between the medium 4 and the processing apparatus 1 may also occur through an external reading device connected to the processing apparatus 1, so as to allow the use of already existing processing apparatuses 1.

The database 3 could be also a database subdivided into a plurality of geographically distributed units. Preferably, the data structure is relational, still more preferably a RDBMS ORACLE 9i, comprising the following tables:

- a table related to the users’ personal data, the information, even the historical one, of which may be rapidly referred to by the health operators;
- a table related to the health operators’ personal data (for instance, regional code, worker status, specialisation, and number of patients of a doctor); and
- a table related to the clinical data of all the reports concerning the users.

The system according to the invention may also embody non ORACLE databases, made accessible through a suitably developed XML interface.

In particular, updating of the users’ clinical data coming from electronic case histories may be carried out through a connection according to the HL7 protocol with an external system.

Data safety and privacy are ensured by methods for encrypting the same during transmissions among the several components of the system. Moreover, personal data are preferably separated from health and clinical data, distributing them on several units. As said, data access level is modulated by recognition of the access entitlement owned by each
operator, through the related identification code.

The system is extremely versatile, allowing, for instance, a doctor or a pharmacist to make also reservations for visits or services and to simultaneously update in real time any operation executed through the medium 4 on the data of the relevant user.

Furthermore, along with the communication among the processing apparatuses 1 and the database 3, the system may also provide that, through the network 2, the processing apparatuses 1 of different health structures may communicate with each other, updating local databases of the same structures (as for instance the reservation ones).

The system is further applicable for the health recognition of users within another country who are citizens of a certain nation. For instance, the portable medium 4 could allow any European citizen, being in another country of the European Union, to receive the medical assistance of the latter, without any more preliminary wearisome bureaucratic paper to be deal with, as it is presently necessary. The same could obviously occur also in a wider territorial extent, allowing, for instance, the health recognition of European citizens in extra-European countries.

The advantages offered by the system according to the invention, that is moreover applicable to the management of health data not only of a human population, but also of an animal population, are extremely significant.

First of all, it allows a high saving of national health system costs, improving organisational and communication abilities of the various health structures.

Moreover, the system according to the invention allows an enhancement in professionalism of the various health operators, most of all of the doctors, increasing their productivity thanks to the immediate availability of patients’ health data.

Still, the system is extremely simple to use, versatile, and safe.

Furthermore, referral and updating of the health data substantially in real time allows the definition of practically immediate diagnoses, promoting a decrease of complications and mortality rate due to delayed diagnoses, and a timely control, if necessary, of all the movements of a patient within the territory served by the system, that may
be extended up to comprise whole national territories.

Finally, easy availability of health data allows to conduct either exact or statistical searches on specific samples of population.

The preferred embodiments have been above described and some modifications of this invention have been suggested, but it should be understood that those skilled in the art can make other variations and changes, without so departing from the related scope of protection, as defined by the following claims.
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CLAIMS

1. System for managing health data of a plurality of individuals of a population, comprising:
   - one or more databases (3), each one of which stores at least one portion of health and/or administrative data of said individuals;
   - a plurality of processing apparatuses (1), each located in a corresponding health site, capable to connect with said one or more databases (3) through a communication network (2); and
   - at least one portable storage medium (4) for each one of said individuals, storing identification data of the individual, said identification data of the individual of said at least one portable storage medium (4) being capable to be read by at least one of said plurality of processing apparatuses (1) for enabling said at least one processing apparatus (1) to refer to and/or update at least one portion of said health and/or administrative data stored in said one or more databases (3).

2. System according to claim 1, characterised in that said portable storage medium (4) comprises at least one processing unit, preferably a microprocessor.

3. System according to claim 1 or 2, characterised in that said portable storage medium (4) comprises at least one electrically erasable programmable read only memory or EEPROM.

4. System according to any one of the preceding claims, characterised in that said portable storage medium (4) further stores at least one software application and/or further data capable to set up said at least one processing apparatus (1) reading the same for referring to and/or updating said at least one portion of said health and/or administrative data stored in said one or more databases (3).

5. System according to any one of the preceding claims, characterised in that said portable storage medium (4) is a smart card.

6. System according to any one of the preceding claims, characterised in that said portable storage medium (4) comprises a communication interface according to the USB standard.

7. System according to any one of the preceding claims, characterised in that said portable storage medium (4) comprises at least one magnetic stripe.

8. System according to any one of the preceding claims,
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characterised in that at least one of said plurality of processing apparatuses (1) comprises at least one input/output or I/O interface port capable to receive said at least one portable storage medium (4) so that said at least one processing apparatus (1) reads said identification data of the individual.

9. System according to any one of the preceding claims, characterised in that at least one of said plurality of processing apparatuses (1) is capable to be connected to an external electronic device for reading said at least one portable storage medium (4), so that said at least one processing apparatus (1) reads said identification data of the individual.

10. System according to any one of the preceding claims, characterised in that at least one of said plurality of processing apparatuses (1) is a processing apparatus selected from the group comprising a computer, a hand-held device, and a cellular telephone.

11. System according to any one of the preceding claims, characterised in that said at least one portion of said health and/or administrative data, that is referred to and/or updated by said at least one processing apparatus (1), depends on at least one identification code of a health operator operating on said at least one processing apparatus (1).

12. System according to claim 9, characterised in that said at least one identification code of the health operator is inserted through a user-id/password type input interface, and/or may be preinstalled in said at least one processing apparatus (1), and/or may be read from a further portable storage medium.

13. System according to any one of the preceding claims, characterised in that said health and/or administrative data of said individuals comprise:

- personal data of said individuals, and/or
- diagnosis and/or analysis and/or report clinical data concerning said individuals, and/or
- data related to reservations and/or health services benefited by said individuals, and/or
- data related to sensitivities or intolerance of said individuals to chemical and/or biological substances, and/or
- data related to therapeutic prescriptions of said individuals, and/or
- data related to an expression of will to be an organ donor.

14. System according to any one of the preceding claims, characterised in that one or more of said individuals whose health and/or administrative data are stored in said one or more databases (3) are health operators, and in that the related health and/or administrative data of said health operators comprise their personal data.

15. System according to any one of the preceding claims, characterised in that at least one of said one or more databases (3) stores at least one portion of health and/or administrative data of said individuals in a data structure of relational type.

16. System according to any one of the preceding claims, characterised in that at least one of said one or more databases (3) stores at least one portion of health and/or administrative data of said individuals in a data structure of object type.

17. System according to any one of the preceding claims, characterised in that said one or more databases (3) are geographically distributed.

18. System according to any one of the preceding claims, characterised in that said at least one processing apparatus (1) is capable to refer to and/or update at least one portion of said health and/or administrative data stored in said one or more databases (3) through a browser graphical interface.

19. System according to any one of the preceding claims, characterised in that said health and/or administrative data of said individuals are capable to be updated through a connection according to the HL7 protocol with an external system storing updating data comprising electronic case histories.

20. System according to any one of the preceding claims, characterised in that at least one portion of said health and/or administrative data of said individuals are transmitted over the communication network (2) in encrypted format.

21. System according to any one of the preceding claims, characterised in that at least two of said plurality of processing apparatuses (1) are capable to connect to each other through said communication network (2).

22. System according to any one of the preceding claims, characterised in that said communication network (2) is at least partially a
wireless, preferably satellite and/or cellular telephony, communication network and/or at least partially a wired, preferably land line and/or fibre-optics telephony, communication network.

23. System according to any one of the preceding claims, characterised in that said communication network (2) comprises the Internet network.

24. System according to any one of the preceding claims, characterised in that said health sites comprise at least one surgery, and/or at least one hospital, and/or at least one specialist's surgery, and/or at least one ambulance, and/or at least one pharmacy, and/or an orthopaedic workshop, and/or at least one medical device provider.

25. Portable storage medium (4), characterised in that it stores identification data of an individual capable to be read by at least one processing apparatus (1) for enabling this one to refer to and/or update at least one portion of health and/or administrative data stored in one or more databases (3), and in that it is capable to be used by the system for managing health data of a plurality of individuals of a population according to any one of claims 1 to 24.

26. Medium according to claim 25, characterised in that it comprises at least one processing unit, preferably a microprocessor.

27. Medium according to claim 25 or 26, characterised in that it comprises at least one electrically erasable programmable read only memory or EEPROM.

28. Medium according to any one of claims 25 to 27, characterised in that it further stores at least one software application and/or further data capable to set up said at least one processing apparatus (1) reading them for referring to and/or updating said at least one portion of said health and/or administrative data stored in said one or more databases (3).

29. Medium according to any one of claims 25 to 28, characterised in that it is a smart card.

30. Medium according to any one of claims 25 to 29, characterised in that it comprises a communication interface according to the USB standard.

31. Medium according to any one of claims 25 to 30, characterised in that it comprises at least one magnetic stripe.

32. Electronic reading device, capable to be connected to at
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least one processing apparatus (1), characterised in that it is capable to
read at least one portable storage medium (4) according to any one of
claims 25 to 31, and in that it is capable to be used by the system for
managing health data of a plurality of individuals of a population according
to claim 9 or according to any one of claims 10 to 24, when dependent on
claim 9.
**INTERNATIONAL SEARCH REPORT**

**A. CLASSIFICATION OF SUBJECT MATTER**

**INV. G06F19/00**

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

G06F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic database consulted during the international search (name of database and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, INSPEC, MEDLINE, COMPENDEX, BIOSIS

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

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Further documents are listed in the continuation of Box C.

See patent family annex.

**Date of the actual completion of the international search**

31 March 2006

**Date of mailing of the international search report**

11/04/2006

**Name and mailing address of the ISA**

European Patent Office, P.B. 5818, Buitenveldertlaan 2 NL - 2280 HV, RIJWIJK
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Authorized officer

Barba, M
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