Systems and methods are disclosed for aiding physicians and other healthcare workers in setting prescriptions of therapeutic and/or preventive regimens. In certain embodiments the invention compares patient genotype, phenotype, proteomic, molecular, and/or profile information with a database of information that associates third party profiles with third party responses to therapeutic and preventive regimens. The comparison information may be used by a physician or other healthcare provider to identify potential safety and/or efficacy effects of a prescribed regimen if undertaken by the patient. The systems and methods provide for the secure storage and directed access of the patient profiles.

1. Provide report comparing information from Patient Database to Third Party Database
2. Authorize healthcare provider to access report
3. Healthcare provider prescribes regimen
4. Healthcare provider reviews report to assess if regimen likely to be safe
   - Yes: Propose better alternatives
   - No: Propose alternatives
5. Healthcare provider reviews report to assess whether regimen is likely to be efficacious
   - Yes: Propose better alternatives
   - No: Propose alternatives
6. Recommend prescription
Provide periodic updated information based on further developments in the medical industry.

Store comparison data regarding potential safety and efficacy effects of regimen(s) on patient.

Make available to authorized healthcare providers upon request.

Obtain patient profile from physical sample.

Compare profile to Third Party Database.

Third Party Database.
Figure 9

1. Healthcare provider proposes regimen
2. Use Third Party Database
3. Compare Third Party Database to Third Party Database to predict outcomes of regimen, store as Comparison Profile
4. Authorize provider to access Patient Profile
5. Provide updated third-party information
6. Add to Third Party Database
7. Monitor patient response
8. Select regimen, establish dosing
9. Report predicted safety and/or efficacy of the proposed regimen
10. Provide alternative regimen(s) based on comparison
11. Process sample to create patient profile, store as Patient Database
12. Provide other patient information
SYSTEM AND METHODS FOR PRESCRIBING THERAPEUTIC AND PREVENTIVE REGIMENS

RELATED APPLICATIONS

[0001] This application is a divisional of U.S. patent application Ser. No. 11/053,465, filed Feb. 7, 2005, entitled “Systems and Methods for Prescribing Therapeutic and Preventive Regimens,” which was a continuation-in-part application of U.S. patent application Ser. No. 10/691,205, filed Oct. 21, 2003, entitled “Systems and Methods for Prescribing Therapeutic and Preventive Regimens,” which was a continuation of U.S. patent application Ser. No. 09/425,085, filed on Oct. 22, 1999 (now issued as U.S. Pat. No. 6,640,211), the entirety of each of the above-identified applications is hereby incorporated in this application by reference.

BACKGROUND

[0002] Today, the pharmaceutical and healthcare industries are rapidly developing new drugs and other therapies that are useful in treating patients. These therapies are quite effective and are promoting better health and extending the life of many patients. However, at the same time, more and more information is being developed about these drugs and therapies, and the burden on physicians and other healthcare providers to maintain a complete understanding of how these drugs and therapies work for each individual patient, is becoming unwieldy. In particular, the efficacy and the safety of each of these new drugs and therapies may vary from patient to patient. For example, VIOXX has been a very successful drug for the purpose of treating pain. However, it has been learned that VIOXX, for certain patients, may lead to an increased risk of high blood pressure, heart attacks, stroke, or other cardiovascular problems. Therefore, although VIOXX might be quite effective for a substantial portion of the population, for others it can be the wrong therapeutic of choice.

[0003] To address this issue, physicians today may collect specimens from a patient and send those specimens to a lab. The lab results come back and they provide the physician with data that can be used to guide the physician to determine if the proposed therapeutic regimen will be effective and safe for that patient. However, the use of such labs adds delay and cost, further, the effective use of the lab result turns largely on the physician’s ability to identify the right tests for the patient specimen. This puts the burden on the physician to be current on all the different possible side effects and safety issues that can arise for particular therapeutic regimens for a particular kind of patient, and on the appropriate lab tests to address those issues. This is an unrealistic burden to place on the health care providers.

[0004] According, there is a need today for a more immediate and more easily accessible system that allows a physician to make a more educated assessment of the efficacy and safety of a particular therapeutic regimen for a specific patient without the time delay and the concern for missing information both of which exist with the present systems. In another aspect, there is also a need to protect the privacy of patient biological information when using it to assess safety and efficacy risks in prescribing a regimen.

SUMMARY OF THE INVENTION

[0005] Systems and methods are disclosed herein to enable a physician or other healthcare provider to make informed decisions about therapeutic and/or preventive measures to prescribe to a patient. The systems and methods allow the healthcare provider to prescribe a regimen to the patient based on information about the patient when compared to information about third parties who have undertaken a similar regimen. The patient information may be any bioprofile derived from a physical sample or otherwise associated with the patient, such as a genotypic profile, a phenotypic profile, a proteomic profile, a molecular profile, a transcriptomic profile, or other profile particular to the patient. Combination profiles may also be provided. The healthcare provider may compare the patient’s bioprofile to one or more bioprofiles of third parties, assess the safety and efficacy of the proposed regimen when undertaken by the third parties having similar bioprofiles to the patient, and assess whether the proposed regimen is likely to be safe and/or efficacious for the patient based on the comparison.

[0006] The systems and methods provide for a databasing and reporting system available to the physician at the site of patient care (e.g., in the doctor’s office) to make and/or assess the comparison. Multiple regimens may be integrated into the database, thereby providing the physician with access to a database that broadly reflects the state of medical care and the knowledge contained in the industry, enabling the physician to provide a more informed prescription of a regimen to the patient, and this at the site of patient treatment (e.g., doctor’s office). In particular, the physician can view the comparative data, comparing the patient’s profile to the profile results experienced by the third parties in the database, to assess likely safety and/or efficacy effects for the patient when undertaking the regimen.

[0007] In one aspect, the systems and methods provide for a portable bioprofile that can be provided to the patient (or authorized third party) prior to a care appointment and presented to the healthcare provider at the site of care. In another aspect, the patient’s bioprofile may be provided in a database under access conditions controlled by the patient and/or authorized party (e.g., prison warden, guardian, parent, etc.). In this respect the patient may have a portfolio that is portable and/or accessible at any healthcare provider’s site without a need for lab testing in connection with each visit. The systems and methods may also provide for controlled access so that only an authorized party (e.g., an authorized healthcare provider) can access the patient’s information, thereby protecting the privacy of the patient’s information. Having such access to the patient’s information, third party database, and comparative data, the physician can make a more educated, hopefully more successful prescription. In certain embodiments, the system may also provide alternative regimens. Alternative regimen may be undertaken by the patient, based on the profile of the patient and the comparative data from the third party database.

[0008] In certain embodiments that invention provides for a method for providing patient prescription, comprising obtaining a physical sample from a source (such as the patient or other authorized provider) and processing said physical sample to generate information representative of a profile associated with the physical sample, obtaining a set of access rights to the source defining conditions under which parties can access the information, said conditions including conditions representative of the parties allowed access and uses for which access is allowed, receiving a request from a party to access the information to perform an analysis on the information to determine one or more of the potential safety
and potential efficacy of a therapeutic or preventive regimen for a patient having the profile associated with the physical sample, comparing the party’s request with the access rights to confirm that the party is authorized to access the information as requested, if the party is authorized, performing the requested analysis on the information, and if the party is not authorized, denying access.

[0009] In certain embodiments the invention provides for a system for aiding a healthcare provider in prescribing a method of treatment, comprising a database having stored therein information representative of a profile associated with a patient, an access control system for defining conditions under which third parties can access the stored information, said conditions including conditions representative of the third parties allowed access and uses for which access is allowed, an interface for receiving a request from a third party to access the stored information to perform an analysis on the stored information to determine the efficacy of a treatment or preventive regimen for a patient having the associated profile. A testing system may also be provided for comparing the third party’s request with the access rights to confirm that the third party is authorized to access the stored information as requested, performing the requested test on the stored information, and providing the analysis results to the healthcare provider. Exemplary systems include a database of third party health information coupled to the testing system to perform the requested test. In certain embodiments the systems and accompanying database(s) are accessible through a network such as the Internet or an internal network which may, in certain embodiments, be accessed at the site at which healthcare is provided.

[0010] In certain embodiments the invention provides for a method comprising obtaining a physical sample from a source (such as a patient, parent or guardian thereof or other authorized provider of the physical sample) and processing said physical sample to generate information representative of a profile associated with the physical sample, obtaining a first database of information associated with third party profiles and information associated with responses by the third parties to one or more regimens, comparing the patient profile to the first database to identify potential safety effects, efficacy effects or both of one or more regimens were the one or more regimens to be prescribed to the patient, and storing information pertaining to the potential safety and efficacy effects in a second database that is accessible only by users authorized by the source that provided the physical sample.

[0011] In certain embodiments the systems and methods allow for the prescription of both preventive and therapeutic regimens, as determined appropriate based on a comparison of the patient’s profile to information in a third party database.

[0012] The invention may be better understood by reference to the exemplary figures and accompanying description, which are not intended to be exhaustive.

**BRIEF DESCRIPTION OF THE FIGURES**

[0013] FIG. 1 depicts a system according to the invention for providing comparative patient data to a healthcare provider.

[0014] FIG. 2 depicts an embodiment of a decision flowchart illustrating an application of a method disclosed herein.

[0015] FIG. 3 is a flow chart illustrating an application of a method disclosed herein.

[0016] FIG. 4 depicts an embodiment of a process whereby a patient’s profile is identified and compared to a third party database provided to a healthcare provider for analysis.

[0017] FIG. 5 depicts an embodiment of a process whereby a physician analyzes comparative patient information and receives information to enable the physician to prescribe a regimen.

[0018] FIG. 6 depicts a third party database applicable to the systems and methods described herein for comparison with patient profiles and proposed regimens.

[0019] FIG. 7 depicts a patient database, including a patient’s profile and other information useful for comparison to third party information for identifying likely safety and/or efficacy effects of a regimen.

[0020] FIG. 8 depicts an embodiment of a process whereby comparative patient information is made available to an authorized physician at the site of patient treatment.

[0021] FIG. 9 depicts an embodiment of a process and applications thereof.

[0022] FIG. 10 depicts an embodiment of an electronic or computerized application of the systems and methods described herein.

**DETAILED DESCRIPTION**

[0023] The systems and methods disclosed herein enable a physician or other healthcare provider to make an informed decision about therapeutic and/or preventive measures to prescribe to a patient. In general, the invention enables a healthcare provider to provide patient care that is informed by a knowledge of the patient’s biological profile and/or other information pertaining to the patient, and informed by reference to a database of information pertaining to third parties and their particular biological profiles and responses to the proposed regimens.

[0024] The systems and methods allow the healthcare provider to obtain patient information, perform an analysis on the patient information, and prescribe a regimen to the patient based on information about the patient as a result of the analysis. The analysis may include comparing information about the patient, such as the patient’s bioprofile, to information about third parties who have undertaken a similar regimen. The patient information may be any bioprofile derived from a physical sample or otherwise associated with the patient, such as a genotypic profile, a phenotypic profile, a proteomic profile, a molecular profile, a transcriptomic profile, or other profile particular to the patient. Combination profiles may also be provided, such as a genotypic profile compiled with a proteomic profile, a proteomic profile coupled to a transcriptomic profile, etc. The healthcare provider may compare the patient’s bioprofile to one or more bioprofiles of third parties, assess whether one or more third parties have undertaken the regimen, and assess whether it is likely to be safe and/or efficacious for the patient based on the comparison.

[0025] The systems and methods provide for a databasing and reporting system available to the healthcare provider at the site of patient care (e.g., the doctor’s office) to make and/or assess the comparison. In particular, the physician or other healthcare provider can view comparative data, which compares the patient’s profile to the profile of third parties and results experienced by the third parties in response to a regimen, to assess whether the patient is likely to encounter safety and/or efficacy difficulties when undertaking the regimen. Data regarding multiple regimens may be integrated.
into the database, thereby providing the physician with access to a database that broadly reflects the state of medical care and the knowledge contained in the industry, thereby enabling the physician to provide a more informed prescription of a regimen to the patient. The regimens may be of any type, such as therapeutic or preventative. In certain embodiments the regimens may include drug treatment, in certain embodiments the regimens may include rehabilitation protocols, dieting, exercise, or other regimens. In certain embodiments the regimens may include combinations of regimens.

[0026] In one aspect, the systems and methods provide for a portable bioprofile that can be provided to the patient (or authorized third party) prior to a care appointment and presented to the healthcare provider at the site of care. In another aspect, the patient’s bioprofile may be provided in a database under access conditions controlled by the patient and/or authorized party (e.g., prison warden, guardian, parent, etc.). In this respect the patient may have a portfolio that is portable and/or accessible at any healthcare provider’s site without the need for lab testing in connection with each visit. The systems and methods provide for controlled access so that only an authorized party (e.g., an authorized healthcare provider) can access the patient’s profile information and comparative data, thereby protecting the privacy of the patient. Having such access to the comparative data, the physician can make a more educated, hopefully more successful prescription based on the information contained in a third party database. In certain embodiments, the system may also provide alternative regimens. Alternative regimens may be prescribed based on the profile of the patient and the comparative data from the third party database.

[0027] FIG. 1 depicts a system according to the invention for obtaining, processing and reporting comparative information about a patient 14. More particularly, FIG. 1 depicts a physical sample storage component 22 which may contain patient tissue, blood or any other physical sample that may be provided. Also depicted is a processing system 12 interfacing with the physical sample storage 22 for processing the sample to identify a patient profile. Testing system 20 and database 18 are provided, both of which interface with processing system 12. Also depicted is a healthcare provider 16 who may be authorized to access the database 18 and processing system 12 to perform tests or other analyses on certain patient information. Also shown in the figure is an access control system 24 interfacing with the processing system 12 and healthcare provider 16. Such access control system 24 features an access control interface 26 which is depicted in the figure as being connected to an electronic or other form of a table 28 that depicts conditions under which third parties can have access to the processing system 12, database 15 and testing system 15, and/or patient information contained therein. As shown in FIG. 1, the access conditions may be established and/or controlled by the patient 14, while in certain embodiments the access conditions may be established and/or controlled by a patient designee or other authorized third party.

[0028] Processing system 12 may contain a number of components for identifying and processing patient profiles. The processing system may provide a component for processing a physical sample to identify a profile associated with the sample, and other information pertaining thereto. The profile may include one or more of a genotypic profile, a phenotypic profile, a transcriptomic profile, a proteomic profile, and/or a molecular profile, or any other bioprofile particular to the patient as may be understood from an analysis of the physical sample, or combination of any of the foregoing.

[0029] Patient 14, also known as a “source” may be the person from whom a physical sample is derived or drawn. The term “patient,” as used herein, refers to the source who, under authority, provides a physical sample for a profile as described herein. The source may be a patient who visits a healthcare professional for treatment or for diagnosis of certain conditions or for therapeutic and/or preventive regimens. In certain embodiments, the source may be a third party who obtains the sample from a patient. The source may be a guardian, parent or a custodian such as a government or other authority (e.g., a prison or police officer, who obtains the sample by authority to do so, or other authorized party).

[0030] Healthcare provider 16, may be a doctor, nurse, nurse practitioner or a physician’s assistant, or any other healthcare provider who interacts with the patient or the source of the sample.

[0031] In certain embodiments, the source (e.g., the patient) provides a physical sample, such as is stored in 22. As noted, the physical sample may be drawn by any known technique, such as tissue sampling, blood type, blood sampling or any other technique. In certain embodiments the patient’s physical sample may be subject to the access control system, such that only parties authorized by the patient may have access to the sample.

[0032] Processing system 12 allows the physical sample from 22 to be subject to one or more tests or techniques for extracting information from the physical sample to identify a patient’s biological profile. In certain embodiments, the testing may be aimed to identify a genotype of the patient, which may be performed by genotyping techniques which are well known in the art. In certain embodiments, processing system 12 may test the patient’s physical sample to identify a proteomic profile, such as by techniques also well known in the art. Other profiles may be obtained, and combinations of profiles may be also used to provide more exhaustive and/or accurate results, such as a combined genotypic and phenotypic profile, or combinations of all or one or more of any type of profile that can be developed. Combined genotypic and proteomic profiles may be provided, etc.

[0033] Database 18 may contain information particular to third parties. Such information may include profiles of the third parties who have undertaken regimens similar to those being proposed by the healthcare provider. In certain embodiments, the database contains information from a plurality of patients having undertaken one or more regimens, and contains a profile for each of the patients referenced therein. In certain embodiments, the profiles of these patients are genotypic, phenotypic, proteomic, etc., or any combination of any desired profile, and may be made available for analysis as described herein.

[0034] Testing system 20 may be adapted through algorithmic or any other applicable technique to compare information from the database 18 with the patient’s profile to access potential safety and/or efficacy effects of the particular regimen.

[0035] Also depicted is an access control system 24, which may be employed to protect the privacy of the patient’s profile information and to limit access thereto to authorized health care providers. As depicted in FIG. 1, an access control interface 26 may be provided to identify conditions under which third parties can have access to the patient’s profile information (28). The health care provider 16 may make a request to the access control interface 26 to obtain access to the patient
profile and, if authorized, the health care provider will be provided access to the desired profile. In certain embodiments the health care provider will be required to identify the intended analysis or an intended comparative test or other type of activities expected to be performed using the information prior to being allowed access thereto, as one or more of the conditions under which the health care provider would be allowed to gain access, pursuant to the conditions chart 28. U.S. Pat. No. 6,640,211 describes examples of systems for authorizing practitioners to have access to genetic information associated with a patient, which may be applied with the systems and methods described herein.

In certain embodiments, the access control system 24 receives a request from a party to access the information contained therein, such as patient profile information, to perform an analysis on the information to determine one or more of a potential efficacy of a therapeutic preventative regimen for a patient having the profile associated with the physical sample. The access control system 24 receives the request through the access control interface 26 and confirms that the party is authorized access the information as requested. If the party is authorized, the party is allowed to have access to the information to make the analysis thereto. If the party is not authorized, access is denied.

The systems and methods may enable healthcare providers to provide better health care prescriptions. The system 10 depicted in FIG. 1 provides a healthcare provider with the ability to test or query the efficacy and/or safety of a particular treatment or prevent regimen for a patient. In an example, the health care provider may be a physician that prescribes a drug for a patient in response to a particular condition diagnosed therein. In such a practice the physician receives authority from the patient (or an authorizing guardian, custodian, etc., of the patient) to access the patient’s profile to compare like profiles of third parties who have undertaken the regimen, and to predict safety and/or efficacy effects if the regimen is prescribed and followed by the patient based on the comparison.

The systems may be implemented through methods, such as that shown in FIG. 2. FIG. 2 depicts a flow diagram illustrating the implementation of a method 30 allowing a physician to access profile information of a patient as compared to information pertaining to third parties to enable the physician to prescribe a particular regimen. As shown in FIG. 2, a report 32 may be prepared from a patient database containing the patient’s profile and, in certain embodiments, other information about the patient as compared to information contained in a third party database. A health care provider may be authorized to access the report 34. Once the health care provider is authorized, it accesses the comparative report 32 to assess whether the regimen is safe, the assessment being based on the report 38. If the report identifies potential safety problems for the patient with respect to the regimen, then alternative regimens may be suggested 42. The proposed regimen may also be assessed as to whether it is likely to be efficacious for the patient, based on the report 40. If the analysis shows that it is not likely to be efficacious, then alternative regimens may be proposed 42. If the analysis shows that the particular regimen is likely to be efficacious then it may be recommended as efficacious for prescription 46, and/or alternative regimens may be proposed 44.

As noted above, the patient’s profile may be compared to information in the third party database to assess the safety and/or efficacy of a proposed regimen 54. The comparison may be illustrated according to the process 50 shown in FIG. 3. FIG. 3 shows a flow chart for process 50, including inputting a patient profile into a Patient Database 51 and identifying a particular condition and proposed regimen for the patient 53, all of which may be input into a testing system such as system 20 shown in FIG. 1. The method also includes providing a Third Party Database 52 containing information identifying third parties, their profiles, regimens they undertook, and results thereof, including safety and efficacy results. Once input, the patient profile 51 and the patient condition and proposed regimen 53 are analyzed in comparison to the third party database 52. In a first step, a user (or processor) identifies whether any of the third parties in the database 52 have received the proposed regimen 53 as is being suggested for the patient. If “no,” then the patient profile 51 is unable to be analyzed according to the system. If the answer is “yes,” the process 50 then assesses 55 whether any of the patients referenced in the third party database 52 have a profile common to that of the patient 14.

The process 50 then identifies responses by third parties who have common profiles 57, then assesses whether any of the third party responses among patients with common profiles 57 suggest that the patient will experience safety problems with the proposed regimen 58. If “yes,” then the information is reported to a provider 56. A step may also be taken to assess whether the third party responses suggest that the regimen will be efficacious for the patient 59. If “no,” then a report is provided to the provider 56. Alternative regimens may also be recommended 60 for the patient’s condition based on a comparison of the profiles as described above. This may be done whether or not the proposed regimen is likely to be efficacious, and whether or not it is likely to be particularly safe.

In certain embodiments, the comparative analysis, such as that shown in FIG. 3, may be made by comparing patient information with information contained in third party databases, and may include comparing information pertaining to the patient (such as a profile) to information associated with a known trait, disease, drug response, or response to a proposed regimen, as such may be identified in a third party database. In certain embodiments the patient profile may be analyzed by comparing the patient’s information to information associated with a known patient response.

As noted, the patient information may include one or more bioprofiles derived from a physical sample or otherwise associated with a patient, such as genotypic profile, a phenotypic profile, a proteomic profile, a molecular profile, a transcriptomic profile, or other profile particular to the patient. In certain embodiments, a genotypic profile may include a list of genetic markers and the particular alleles of those markers found in a sample from the patient. In certain embodiments, a phenotypic profile may include a list of phenotypes, or observable characteristics, and the values of those phenotypes measured for the patient. In certain embodiments, a proteomic profile may include a list of proteins and measured levels of those proteins in a sample from the patient, and may also include information on the distribution of those proteins within cells, tissues, bodily fluids, and organs of the patient. In certain embodiments, a transcriptomic profile may include a list of RNAs and measured levels of those RNAs in a sample from the patient, and may also include information on the distribution of those RNAs within cells, tissues and organs of the patient. In certain embodiments, a molecular profile may include a list of molecular species and their levels
and/or distribution within the cells, tissues, bodily fluids, and organs of the patient. In certain embodiments, a bioprofile may include lists of genetic markers, phenotypes, proteins, molecular species, and/or RNAs, and their particular forms, levels, and distributions within any one or more of the cells, tissues, bodily fluids, and organs of a patient.

In some cases a patient’s profile may include a genetic mutation, and the presence of the mutation in a third party profile may be used as a basis for selecting third parties from the database that have received the proposed regimen. A selected third party’s response to the regimen may then be evaluated for potential safety and/or efficacy effects that may arise if the patient undertakes the regimen. In certain embodiments the patient’s profile may include the presence or absence of one or more proteins or biomolecules, one or more markers, or any other characteristics, and the presence or absence of the characteristic may be compared to third party information to identify third parties having like characteristics, and the selected third parties’ responses may be identified to assess the likely response by the patient. In certain embodiments the patient’s information may include transcripts of one or more RNA or eDNA expressed by the patient, and the presence of the transcript in a third party profile may be used as a basis for selecting third parties from the database. In certain embodiments the patient profile may contain a combination of profiles, and the third party database of information may also contain profile combinations to improve accuracy of the methods. In certain embodiments, the systems and methods provide for identifying a patient’s entire genome and inputting such information into a database subject to access restrictions.

In certain examples, the systems and methods disclosed herein may be used to provide a patient profile for one or more identified cellular components in a patient, and the profile may be used to select an appropriate regimen for a patient. Exemplary cellular components may include CYF2D6, CYF2C9, Factor V, Prothrombin, MTHFR, TMP, UGT1A1, COMT, SULT1A1, and any other proteins or enzymes. In certain embodiments, forming a profile for a cellular protein or enzyme includes identifying variant alleles for the particular protein or enzyme. In the case of CYP2D6, variants on alleles 3, 4, 5, 6, 7, and/or 8 may be identified and included in a database pertaining to the patient. Similarly, a third party database may include variations in one or more alleles and correlate the allele variations with responses to various regimens undertaken by the third parties. Other examples abound, such as certain factors implicated in drug metabolism. These factors may include, for example, CYP2C9 and variations in alleles 2, 3, 5, and/or 9; in the case of CYF2C9, and variations in alleles 2 and/or 3. By identifying mutations in one or more of these components a healthcare provider may be able to avoid prescribing medications (such as Zoloft, EffexorXR, Resperidal, Oxycontin, Paxil, Viagra) that are known to be poorly metabolized by patients having one or more of such mutations. The healthcare provider may be able to prescribe appropriate medications to provide for optimal metabolism.

Numerous other examples abound, such as in the case of cellular components that when combined with certain oral contraceptives impair thrombotic or obstetrical complications. In the case of Factor V, mutations in allele 1691G>A may be identified; for Prothrombin, 20210G>A; for MTHFR, 677C>T. Where one or more of these mutations are identified in the patient profile, the healthcare provider may elect to avoid prescribing an oral contraceptive that is identified in the third party database as correlating with such complications when taken by a patient having the identified mutation.

Similarly, for oncology therapies, allele variations selected from 238G>C; 460G>A; and 719A>G may give rise to mutations in TPMT, which can lead to toxicity for Leukemia patients taking (purinefeul). If a healthcare provider identifies that a patient profile has one or more of such mutations, the healthcare provider may elect to prescribe an alternative medication. Similarly, alterations in UGTIAI may be included in a profile, along with an identified variant in allele 28: COMT may be included, along with variant in allele Val108/135Met.

Anti-depressant prescriptions may also be applied using the systems and methods. For example, variants in RHTTLPR (such as a variant in Promoter ins/del) and/or TPH1 may impair the efficacy of Clomipramine, Fluoxetine, and Paroxetine. Where a patient has such a variation, as identified in the profile, the patient may be prescribed alternative regimen.

In certain embodiments, combination profiles may be provided. In certain embodiments, combinations of the foregoing and/or other profiles may be adapted and included. For example, the systems and methods may be used to provide a more effective oncology regimen and an appropriate anti-depressant for a leukemia patient, such information being obtained by comparing the patient’s profile to a third party database. The patient’s profile for drug metabolism enzymes (e.g., CYP2D6, CYP2C9) may also be included and used in the comparison to a third party database. Similarly, a preventive regimen may also be prescribed for the patient, such as a particular diet and/or exercise regimen, based on a comparison to the third party database, and delivered to the healthcare provider upon prescription of an oncology product and an appropriate antidepressant. In this example, the healthcare provider is able to provide a comprehensive, holistic regimen(s) for a patient and customize the regimen(s) based on the patient’s profile. As used herein, in certain embodiments the notion of comparing to a third party database may include comparing a patient’s profile and identified condition and a proposed regimen to a database of third party information, the third party information including third party profiles, regimens undertaken by the third parties, and the safety and/or efficacy of the results of such regimens undertaken by the third parties.

In certain embodiments the patient information may be analyzed by comparing it to information associated with a known indication of efficacy. In certain embodiments the patient information may be analyzed by comparing it to the third party information to identify at least one marker associated with a response to one or more therapeutic agents such as drugs, biologics, etc. In certain embodiments one or more markers are identified as pertaining to a patient condition and may be associated with a particular disease. In certain embodiments the patient information may be analyzed by identifying one of a number of genetic markers associated with certain phenotypes associated with the patient. Those skilled in the art will understand that the comparative information available through the use of the systems and methods described herein may allow a physician to access the likelihood of success of a proposed regimen.

FIG. 4 more particularly describes the an embodiment of the systems and methods described herein through a
process flow chart 100. As shown in FIG. 3, the health care provider may propose a therapeutic or preventive regimen 110 and seek to access 112 the information of a patient 104 such as a patient profile which is derived from a patient sample 102. If the health care provider is authorized, then the provider is given access to the patient information 108. An authorized physician, such as has been authorized through 112, is then authorized to compare the patient profile to a third party database to identify potential safety and/or efficacy of the proposed regimen 108. Such analysis may be made, for example, through the decision methodology shown in FIG. 3. Upon completion of the comparison, potential safety and/or of the proposed regimen is identified 114, and alternative regimens may be proposed 116. The access obtained by the health care provider may be obtained through the system shown in FIG. 1 in certain embodiments.

[0051] FIG. 5 more particularly describes the method exemplified in FIG. 4 and identifies additional features that might be applied in certain embodiments. For example, as shown in FIG. 5, a patient sample 102 may be processed to create a patient profile 104 and stored in a retrievable patient database 105. In certain embodiments the retrievable database may also contain other information pertaining to the patient 107. Such information may be derived from sources such as clinical data, patient anecdotlal information, information directly from the patient or the patient’s guardian, or other sources of information about the patient and, in particular, the patient’s health care. Such other information may also include interpretations made by the healthcare provider of the report provided to the healthcare provider.

[0052] As depicted in FIG. 5, when a health care provider proposes a therapeutic or preventive regimen 110, and is authorized 112 to access the patient’s information 105, the health care provider then obtains access to comparative information or is allowed the opportunity to compare 108 the patient’s information to information in a third party database 106. Upon completion of the comparison, the health care provider may obtain a report identifying potential safety and/or efficacy effects of the proposed regimen 114, and may also be provided alternative regimens that may be appropriate for the patient 116. Upon receipt of such report 114 and such proposed alternatives 116, the health care provider may select and apply an appropriate regimen 120 based on the comparison. As depicted in FIG. 5, the patient’s response to the prescribed regimen may thereafter be monitored and reported 122, and in certain embodiments such information may be contributed to the third party database 106 for future use.

[0053] As noted previously, the health care provider’s prescription may be based on an analysis made of a third party database. FIG. 6 shows an embodiment of a suitable third party database 150 and particular components and sources of information contained therein. As shown in FIG. 6, the third party database 150 may be derived from third party profiles 151, such as those described previously (genotypic, phenotypic, etc.). Such third party database 150 may also include safety and efficacy results information from one or more therapeutic and/or preventive regimens 152 that were undertaken by one or more third parties, and information that identifies those particular regimens. Also shown in FIG. 6, the safety responses 153 of the third parties who undertook the various regimens 152 may also be included in the third party database 150. Additionally, efficacy results 154 of the various third party regimens that were undertaken 152 may be included in the database 150. The information contained in the third party database 150 may be updated from time to time as additional medical information is developed in the medical literature, in clinical testing and treatment facilities, etc. 155. Also, as noted previously, the patient who undertakes a proposed regimen based on the comparison shown in FIG. 5 may also exemplify response data over time, which may be monitored and reported 157. Such information may be added to the third party database 150, along with the patient profile 156. As shown in FIG. 6, access to the third party database 150 may also be controlled 158 through methods and systems similar to those described previously, and such information contained in the third party database 150 may be used for research 159, patient care 160, or other uses as authorized by persons holding authority to authorize usage of the third party database 150. In this respect the systems and methods also provide for large-scale surveillance of drug safety and efficacy.

[0054] Similarly, as noted above, a patient database may be formed and used to assimilate information pertaining to the health of the particular patient being treated and/or diagnosed and monitored by the health care provider. FIG. 7 depicts a patient database 130 containing information pertinent to the patient’s profile 132, such as that described previously (phenotypic, genotypic, and other profiles). The patient database 130 may also contain information from a source other than the physical sample, such as health history information pertaining to the patient 134, anecdotal health information pertaining to the patient 136 and other information applicable thereto. In certain embodiments health history information 134 may be derived from a formal medical record such as may be obtained from a former or current health care provider. In certain embodiments, health history information 134 may be updated from time to time. As also shown in FIG. 6, the anecdotal or other health information may be derived from any number of sources such as the patient, the patient’s family member, a relative, a guardian, publicly available databases or other sources 140 in other embodiments, the source other than the physical sample may include information depicting the patient’s response to the proposed regimen. In certain embodiments the patient’s information is provided by a legal custodian or authorized government official.

[0055] As described above in FIG. 5, the patient’s response to the proposed regimen may be monitored and stored and made available to the physician for later comparative usages and/or for future prescriptions. In certain embodiments, such comparative information may allow the health care provider to compare the patient’s information against a database of information is associated with a particular therapeutic, a particular treatment regimen, a particular preventive health care technique (such as dieting, exercise, etc.), or any other therapeutic or preventive measure.

[0056] As noted, the systems and methods may provide for a more convenient and accessible and more source of comprehensive information for healthcare providers who propose regimens to patients. In certain embodiments the healthcare provider may obtain and compare patient information (such as a profile) to third party information during and at the site of patient care without the need for additional and time consuming lab work. In certain embodiments the healthcare provider may obtain access to the patient’s profile, comparative information (compared to third party information) and/or other information through a report generated at or prior to seeing the patient. Any of such embodiments are considered an embodiment of “performing an analysis” on patient informa-
tion, as described herein. FIG. 8 depicts an embodiment 170 of the methods and systems described herein used to obtain a report generated prior to a healthcare provider meeting with the patient. The patient profile referenced in FIG. 8 may be obtained from a physical sample 172 and compared 176 to a third party database 174, the comparative information may be provided to or made immediately available to the patient, stored 178 to provide access 180 at a later time to a healthcare provider or to others (including the patient him/herself). The patient may obtain an updated comparative profile through the process of FIG. 7 at any time, and the report may be made portable to the patient and/or made available to others through controlled access systems as described herein.

Accordingly, the healthcare provider may obtain access to comparative information to be contained in a report at the site where the patient is being diagnosed and/or where a particular regimen is being prescribed. For example, the systems and methods herein may enable a doctor to access important patient information from a computer terminal in the doctor’s office and use the information to make an informed prescription without having to spend extensive time sending a specimen to a lab and awaiting the arrival of a lab report. Furthermore, the third party database may be expanded and updated periodically 182 as medical progress continues and thereby allow the healthcare provider to take advantage of current knowledge of safety and efficacy of regimens in making prescription decisions. In this respect, a healthcare provider’s prescriptions may be based on current information.

In certain embodiments, the invention provides for a method which comprises obtaining a physical sample from a patient, which may be a third party authorized to obtain a physical sample from the patient, and processing the physical sample to generate information representative of a profile associated with the physical sample, obtaining a first database of information associated with third party profiles and information associated with responses by the third parties to one or more regimens, comparing the patient profile to the first database to identify potential safety or efficacy effects (or both) with one or more regimens to be prescribed to the patient, and storing information pertaining to the potential safety and/or efficacy effects of the regimen in a database (a second database) that is accessible only by users who are authorized by the patient and/or by a person authorized by the patient to obtain the patient's physical sample.

In certain embodiments, the first database is updated periodically to include additional information generated in medical literature or clinical settings that is associated with regimen responses and patient profiles. Such information may be provided electronically, such as through a network. In certain embodiments the third party database is updated periodically in response to changes in the patient’s response to a particular regimen. In certain embodiments the invention provides for receiving a proposed regimen from an authorized health care provider and providing a report that identifies one or more of potential safety and potential efficacy effects of the proposed regimen for a particular patient.

FIG. 9 shows an embodiment of the process set forth in FIG. 8 with more particular demonstration of applications thereof. In particular, FIG. 9 shows the processing of a patient sample 202 to create a patient profile. The patient profile may include, a genotypic profile, proteomic profile, transcriptomic profile, molecular profile, etc. and to store the patient profile in a patient database 204. Patient database 204 may be updated and supplemented by other information pertaining to the patient 205. Also depicted is a third party database 206 which interfaces with the patient database to allow a comparison 208 to predict outcomes of regimens if applied to the patient, and allows for the storage of such comparison information as a comparison profile 208. FIG. 9 also depicts a healthcare provider proposing a therapeutic or preventive regimen 210, and shows that the healthcare provider must be authorized to access the comparison profile 212 in order to access the comparison profile to assess the likely safety and/or efficacy of the proposed regimen. Also shown in FIG. 9 once the authorized healthcare provider gains access to the information contained in the patient database, the third party database, and/or the comparison profile, the authorized healthcare provider may obtain a report 214 detailing potential safety and/or efficacy effects of a proposed regimen. The healthcare provider may also obtain alternative recommended regimens based on the alternatives 216. Upon receipt of such report 214 and/or such comparison 216, the healthcare provider may select a regimen, apply the regimen, or modify the regimen, or establish a dosing procedure for applying the regimen, as depicted in 220. After the regimen is established and applied, the patient response may be monitored 222 and added to third party database 224 along with the patient’s profile.

The third party database 206 may be updated by obtaining patient information 224, as well as from updated third party information 228 as may be derived from the medical industry. The third party database 206 may also be used as a source of information for conducting research 226. Such research may include for example identifying biomarkers, establishing dosing regimens for wide spread therapeutic applications, or any other research desired by those who have access to the database. In certain embodiments, the systems and methods may allow for the use of the comparison profile 208 to predict potential serious adverse events which may arise from a regimen, and make those available to other third party patients who may tend to undertake a particular regimen. In certain embodiments, the third party database may include results from the patient’s use of the regimen and may be used to validate biomarkers as predictive of a course of therapeutic intervention for one or more other patients. Standard statistical analyses may be employed to conduct the validation analysis.

The methods and disclosed herein may also be implemented electronically. In certain embodiments the systems and methods may be implemented through a computerized network, as depicted in FIG. 10. FIG. 10 depicts a computerized system 300, similar to the testing system 20 shown in FIG. 1. Shown in FIG. 10 in particular is a network 304 which interfaces with a processor 302 and a set of databases, including third party database 306, such as that described in FIG. 6, a patient database 308 such as that described in FIG. 7, and a comparison profile 310 such as is described in FIG. 9. Also shown in FIG. 10, processor 302 connects to memory 307, storage device 309, display 301, input device 303, and cursor control 305.

A computerized system as shown in FIG. 10 may be used to compare the third party database with the patient database to generate the comparison profile 310, and may report such comparison profile to an authorized health care provider, as is described previously. More particularly, as shown in FIG. 10, a physician or healthcare provider may input a request to access patient information through the input
device 303. Input device 303 inputs the information through processor 302 and connects via network 304 to patient profile 310, and/or directly to the third party database 306 and/or to the patient database 308.

[0064] Prior to obtaining such information, the healthcare provider obtains authorization to access patient information according to the processes and methods described previously herein. Upon accessing the comparison profile 310, or other desired information, the healthcare provider may input through device 303 information pertaining to the proposed regimen for the patient, the patient’s condition, or other information as applicable. Upon receipt of the input information, the processor 302 will extract, through network 304, comparison profile 310 and any other information available to provide the healthcare provider with information for predicting the safety and/or efficacy of the proposed regimen. A report derived there from may be provided to the user, such as through display 301. In addition, as described previously herein, the processor 302 through network 304 may receive information pertaining to alternative regimens that the healthcare provider may suggest to the patient for the particular condition, such information being provided by considering the patient profile derived from the patient database 308 as compared to third party database 306 and formulated in certain embodiments into comparison profile 310. Such third party database may include patient profiles and regimens under taken by the patients identified therein.

[0065] The figures describe exemplary embodiments of the invention but are not limiting. One of ordinary skill in the art will understand that the braces and methods described herein can be adapted and modified for other applications, including for use with any type of therapeutic or preventive regimen, any patient bioprofile, and/or any health information obtained from a third party. Such additions and modifications will not depart from the scope hereof. Accordingly, the description and examples set forth herein are for illustration purposes only, and are not to be understood as limiting in any way. All references cited herein are incorporated by reference in their entirety herein.

1. A system for aiding a healthcare provider in prescribing a method of treatment, comprising,
   a database having stored therein information representative of a profile associated with a physical sample;
   an access control system for defining conditions under which third parties can access the stored information, said conditions including conditions representative of the third parties allowed access and uses for which access is allowed;
   an interface for receiving a request from a third party to access the stored information to perform an analysis on the stored information to determine the safety and efficacy of a treatment or preventive regimen for a patient having the associated profile; and
   a testing system for comparing the third party’s request with the access rights to confirm that the third party is authorized to access the stored information as requested, performing the requested test on the stored information, and providing the analysis results to the healthcare provider.

2. The system of claim 1, further comprising a database of third party health information coupled to the testing system to perform the requested test.

3. The system of claim 1, wherein the database is accessible through a network.

4. A method comprising
   obtaining a physical sample from a provider and processing said physical sample to generate information representative of a profile associated with the physical sample;
   obtaining a first database of information associated with one or more third party profiles and information associated with responses by one or more third parties to one or more regimens;
   comparing the patient profile to the first database to identify potential safety effects, efficacy effects or both of one or more regimens were the one or more regimens to be prescribed at the patient from which the physical sample is obtained; and
   storing information pertaining to the potential safety and efficacy effects in a second database that is accessible only by users authorized by the provider.

5. The method of claim 4, wherein the first database is updated periodically to include additional information generated in medical literature or a clinical setting.

6. The method of claim 5, wherein the second database is updated periodically in response to changes in the first database.

7. The method of claim 4, wherein the profile associated with the physical sample includes information selected from one or more of a genotypic profile, phenotypic profile, proteomic profile, transcriptomic profile and molecular profile.

8. The method of claim 4, including receiving a proposed regimen from an authorized healthcare provider and providing a report that identifies one or more of potential safety and potential efficacy of the proposed regimen for the patient.

9. The method of claim 5, wherein the report provides one or more alternative courses of action to the proposed regimen.

10. The method of claim 4, wherein the profile associated with the physical sample comprises information selected from one or more of a genotypic profile, phenotypic profile, proteomic profile and molecular profile.

11. The method of claim 4, wherein the one or more regimens includes at least one therapeutic regimen and at least one preventive regimen.

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