

INTEGRATED HEALTH DATA CAPTURE AND ANALYSIS SYSTEM

CROSS-REFERENCE

[0001] This application claims the benefit of U.S. Provisional Application No. 61/253,015, filed October 19, 2009, which application is incorporated herein by reference in its entirety.

BACKGROUND OF THE INVENTION

[0002] An epidemic of infectious diseases capable of spreading across a large region, e.g., a continent or the entire world, can be hugely costly to societies. Such incidences include pandemics of influenza, smallpox, tuberculosis, human immune deficiency virus (HIV), and Severe Acute Respiratory Syndrome (SARS). The World Bank estimated in 2008 that a flu pandemic could cost \$3 trillion and result in a nearly 5% drop in world gross domestic product (GDP). The World Bank further estimated that more than 70 million people could die worldwide in a severe pandemic. Others have estimated that a flu pandemic could cause an economic recession in the United States, costing the country at least \$500 billion to \$675 billion in the near term. In 2003, SARS disrupted travel, trade and the workplace in the Asia Pacific region and cost the region about \$40 billion. The SARS pandemic lasted for six months, killing at least 1000 of the 8,000 people it infected in 25 countries. The city of Toronto, CA was closed to air traffic for several weeks and suffered significant financial loss.

[0003] In 2009, the spring flu season cost billions of dollars even though it only lasted only a few weeks. The 2009-2010 winter flu season is anticipated to start by late August and could run through April 2010. Even if working vaccines are available, their supplies are expected to be limited and cannot be expected to stop the flu for several months. Economic losses can be minimized if the flu can be contained through proactive screening that allows for effective anti-viral administration and narrowly targeted quarantines.

[0004] Economic loss due to "avoidance behaviors" is even greater than the cost of treating flu victims. The cost includes reducing air travel, avoiding travel to infected destinations and reducing consumption of services, such as mass transit, dining out, shopping, etc. According to the World Bank, if a flu epidemic approached the 2.5% mortality rates similar to 1918-19 flu, avoidance behaviors would cost a region five times more than losses from mortality or work absenteeism.

SUMMARY OF THE INVENTION

[0005] There is a pressing need for an infrastructure to mitigate the spread of infectious diseases such as influenza when it occurs. Embodiments of The present invention meets this need through an integrated system that provides real-time sampling, modeling, analysis, and/or recommended interventions. The system can identify active cases in an outbreak through pro-active sampling in high risk locations, such as schools or crowded commercial areas, and can allow for sampling and quarantine of surrounding cases to help eradicate the outbreak. The system can also suggest an appropriate response for deployment of scarce resources and predict the impact of such mitigation both in terms of reduction of mortality and

morbidity and economic impact. Furthermore, the systems of the present invention can help the government provide accurate, more reliable, and timely information that may reduce unnecessary avoidance behavior and save billions of dollars.

~~[0006] In one aspect, the present invention provides a system for modeling a progression of a disease within a population, comprising: a static database component comprising static data related to the disease and/or the population; a dynamic database component comprising dynamic data about the population and individual subjects; and a computer modeling component that is configured to model the data in the static database component and the dynamic database component, thereby modeling the disease within the population. The disease can be an infectious disease or a chronic disease.~~

[0006] In one aspect, there is provided a system for modeling a progression of a disease within a population, comprising:

- a plurality of point-of-care devices, each comprising at least a programmable processor and a fluid transfer device;
- an external device configured to be in communication with said plurality of point-of-care devices;
- a static database component comprising static data related to the disease and/or the population;
- a dynamic database component comprising dynamic data about the population and individual subjects; and
- a computer modeling component that is configured to model the data in the static database component and the dynamic database component, thereby modeling the disease within the population,
- wherein the external device is configured to provide instructions to said programmable processor to implement a change in assay protocol based on output from the computer modeling component without having to provide new point-of-care-devices, and
- wherein said instructions to the programmable processor comprises at least a step of transferring a bodily fluid sample to an individual assay unit.

[0007] In some embodiments, the infectious disease agent or an analyte thereof comprises an adenovirus, *Bordella pertussis*, *Chlamydia pneumoniae*, *Chlamydia trachomatis*, Cholera Toxin, Cholera Toxin β , *Campylobacter jejuni*, Cytomegalovirus, Diphtheria Toxin, Epstein-Barr NA, Epstein-Barr EA, Epstein-Barr VCA, *Helicobacter Pylori*, Hepatitis B virus (HBV) Core, Hepatitis B virus (HBV) Envelope, Hepatitis B virus (HBV) Surface (Ay), Hepatitis C virus (HCV) Core, Hepatitis C virus (HCV) NS3, Hepatitis C virus (HCV) NS4, Hepatitis C virus (HCV) NS5, Hepatitis A, Hepatitis D, Hepatitis E virus (HEV) orf2 3 KD, Hepatitis E virus (HEV) orf2 6 KD, Hepatitis E virus (HEV) orf3 3KD, Human immunodeficiency virus (HIV)-1 p24, Human immunodeficiency virus (HIV)-1 gp41, Human immunodeficiency virus (HIV)-1 gp120, Human papilloma virus (HPV), Herpes simplex virus HSV-1/2, Herpes simplex virus HSV-1 gD, Herpes simplex virus HSV-2 gG, Human T-cell leukemia virus (HTLV)-1/2, Influenza A, Influenza A H3N2, Influenza B, *Leishmania donovani*, Lyme disease, Mumps, *M. pneumoniae*, *M. tuberculosis*, Parainfluenza 1, Parainfluenza 2, Parainfluenza 3, Polio Virus, Respiratory syncytial virus (RSV), Rubella, Rubeola, Streptolysin O, Tetanus Toxin, *T. pallidum* 15 kd, *T. pallidum* p47, *T. cruzi*, Toxoplasma, or *Varicella Zoster*.

[0008] In other embodiments, the disease is an infectious disease comprising a microorganism, a microbe, a virus, a bacterium, an archaeum, a protozoan, a protist, a fungus or a microscopic plant. The virus can comprise influenza or HIV. The bacterium can comprise mycobacterium tuberculosis. The protozoan can comprise malaria.

[0009] In still other embodiments, the disease is a chronic disease or condition comprising diabetes, prediabetes, insulin resistance, metabolic disorder, obesity, or cardiovascular disease.

[0010] The static database component of the invention can include information about the individuals in the population. The information about the individuals in the population can include one or more of age, race, sex, location, genetic factors, single nucleotide polymorphisms (SNPs), family history, disease history or therapeutic history.

[0011] The static database component can also comprise information about the disease. The information about the disease can include one or more of virulence, contagiousness, mode of transmission, treatment availability, vaccine availability, death rate, recovery time, cost of treatment, infectivity, rate of spread, rate of mutation, and past outbreak.

exposed individuals earmarked for surveillance, asymptomatic individuals earmarked for surveillance, early infected individuals earmarked for surveillance, late infected individuals earmarked for surveillance, prophylactic individuals earmarked for surveillance, vaccinated individuals earmarked for surveillance, protected individuals earmarked for surveillance, susceptible individuals in whole neighborhood quarantine earmarked by mitigation policies for action, early exposed individuals in whole neighborhood quarantine earmarked by mitigation policies for action, late exposed individuals in whole neighborhood quarantine earmarked by mitigation policies for action, asymptomatic individuals in whole neighborhood quarantine earmarked by mitigation policies for action, early infected individuals in whole neighborhood quarantine earmarked by mitigation policies for action, late infected individuals in whole neighborhood quarantine earmarked by mitigation policies for action, prophylactic-treated individuals in whole neighborhood quarantine individuals earmarked by mitigation policies for action, cumulative number of therapeutic doses administered, cumulative number of antivirals and/or antibiotics administered, cumulative number of home quarantined asymptomatic individuals, cumulative number of home quarantined symptomatic individuals, cumulative number of total infected individuals, cumulative number of infected individuals who are not quarantined, cumulative number of infected individuals with some action taken, cumulative number of hospitalized individuals, and cumulative number of deaths.

~~[0029] In another aspect, the present invention provides a system for controlling spread of influenza within a population, comprising: a static database component comprising static data related to the influenza and/or the population; a dynamic database component comprising dynamic data about the population; and a computer modeling component that is configured to model the data in the static database component and the dynamic database component, thereby modeling the incidence of the influenza within the population.~~

~~[0030] In still another aspect, the present invention provides a system for controlling spread of human immunodeficiency virus (HIV) within a population, comprising: a static database component comprising static data related to the HIV and/or the population; a dynamic database component comprising dynamic data about the population; a computer modeling component that is configured to model the data in the static database component and the dynamic database component, thereby modeling the incidence of the HIV within the population.~~

~~[0031] In yet another aspect, the present invention provides a system for controlling spread of hepatitis within a population, comprising: a static database component comprising static data related to the hepatitis and/or the population; a dynamic database component comprising dynamic data about the population; and a computer modeling component that is configured to model the data in the static database component and the dynamic database component, thereby modeling the incidence of the hepatitis within the population.~~

~~[0032] In an aspect, the present invention provides a system for controlling spread of diabetes within a population, comprising: a static database component comprising static data related to the diabetes~~

[0029] In another aspect, there is provided a system for controlling spread of influenza within a population, comprising:

- a plurality of point-of-care devices, each comprising at least a programmable processor and a fluid transfer device;

- an external device configured to be in communication with said plurality of point-of-care devices;

- a static database component comprising static data related to the influenza and/or the population;

- a dynamic database component comprising dynamic data about the population; and

- a computer modeling component that is configured to model the data in the static database component and the dynamic database component, thereby modeling the incidence of the influenza within the population,

- wherein the external device is configured to provide instructions to said programmable processor to implement a change in assay protocol based on output from the computer modeling component without having to provide new point-of-care-devices, and

- wherein said instructions to the programmable processor comprises at least a step of transferring a bodily fluid sample to an individual assay unit.

[0030] In still another aspect, there is provided a system for controlling spread of human immunodeficiency virus (HIV) within a population, comprising:

- a plurality of point-of-care devices, each comprising at least a programmable processor and a fluid transfer device;

- an external device configured to be in communication with said plurality of point-of-care devices;

- a static database component comprising static data related to the HIV and/or the population;

- a dynamic database component comprising dynamic data about the population; and

- a computer modeling component that is configured to model the data in the static database component and the dynamic database component, thereby modeling the incidence of the HIV within the population,

- wherein the external device is configured to provide instructions to said programmable processor to implement a change in assay protocol based on output from the computer modeling component without having to provide new point-of-care-devices, and

- wherein said instructions to the programmable processor comprises at least a step of transferring a bodily fluid sample to an individual assay unit.

[0031] In yet another aspect, there is provided a system for controlling spread of hepatitis within a population, comprising:

- a plurality of point-of-care devices, each comprising at least a programmable processor and a fluid transfer device;
- an external device configured to be in communication with said plurality of point-of-care devices;
- a static database component comprising static data related to the hepatitis and/or the population;
- a dynamic database component comprising dynamic data about the population; and
- a computer modeling component that is configured to model the data in the static database component and the dynamic database component, thereby modeling the incidence of the hepatitis within the population,

wherein the external device is configured to provide instructions to said programmable processor to implement a change in assay protocol based on output from the computer modeling component without having to provide new point-of-care-devices, and

wherein said instructions to the programmable processor comprises at least a step of transferring a bodily fluid sample to an individual assay unit.

[0032] In an aspect, there is provided a system for controlling spread of diabetes within a population, comprising:

- a plurality of point-of-care devices, each comprising at least a programmable processor and a fluid transfer device;
- an external device configured to be in communication with said plurality of point-of-care devices;
- a static database component comprising static data related to the diabetes and/or the population;
- a dynamic database component comprising dynamic data about the population; and
- a computer modeling component that is configured to model the data in the static database component and the dynamic database component, thereby modeling the incidence of the diabetes within the population.

wherein the external device is configured to provide instructions to said programmable processor to implement a change in assay protocol based on output from the computer modeling component without having to provide new point-of-care-devices, and

wherein said instructions to the programmable processor comprises at least a step of transferring a bodily fluid sample to an individual assay unit.

~~and/or the population; a dynamic database component comprising dynamic data about the population;~~
and a computer modeling component that is configured to model the data in the static database
component and the dynamic database component, thereby modeling the incidence of the diabetes within
the population.

INCORPORATION BY REFERENCE

[0033] All publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent, or patent application was specifically and individually indicated to be incorporated by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

[0034] The novel features of the invention are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

[0035] Figure 1 illustrates a simplified model representation.

[0036] Figure 2 illustrates a model representation taking into account various states and transitions between states.

[0037] Figure 3 illustrates an assay for H1N1 antigen using sandwich complexes in four different configurations.

[0038] Figure 4A illustrates an assay for host anti-virus antibodies. The figure illustrates a spike recovery assay for host anti-H1N1 antibodies. Shown is a version using α -H1 / α -N1 configuration. Figure 4B illustrates direct assays for α -H1N1 antibodies illustrating sandwich complexes.

[0039] Figure 5 illustrates an exemplary device that can be used in the present invention. The exemplary devices comprise assay units, reagents unit, and other modular components.

[0040] Figure 6 illustrates two side-cut away views of the exemplary device that can be used in the present invention. The exemplary device comprises cavities in the housing of the device shaped to accommodate an assay unit, a reagent unit, and a sample tip.

[0041] Figure 7A demonstrates an exemplary assay unit that comprises a small tip or tubular formation. Figure 7B demonstrates an example of a sample tip as described herein.

[0042] Figures 8A and 8B illustrate two examples of a reagent unit comprising a cup.

[0043] Figure 9 illustrates a thin film, for example, contamination, within the tip when a liquid is expelled and another liquid aspirated.

[0044] Figure 10 demonstrates an example of a system comprising a device and a fluid transfer device.

[0045] Figure 11 illustrates an exemplary system of the invention comprising a heating block for temperature control and a detector.

[0046] Figure 12 demonstrates an exemplary a system wherein a patient delivers blood to a device and then the device is inserted into a reader.