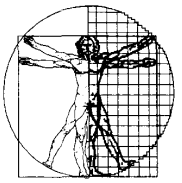

A Literature Review: Robots in Medicine

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Robot usage outside of the automobile, appliance, undersea, space, and hazardous materials industries has increased over the past decade. A significant contributing factor to this increazse use is the robot's ability to dynamically interact with its environment in a precise manner. Examples of robot applications in diverse fields can be found in the *International Encyclopedia of Robotics: Applications and Automation* [1]. The study of robotics requires a multi-disciplinary background in engineering and a thorough knowledge of the task that the robot is designed to perform. For example, a research team at the University of Western Australia has developed an eight axes hydraulic robot system, named ORACLE, to shear sheep [2]. To design a robot for this purpose one has to have a thorough understanding of the shearing process; knowledge of engineering alone will not suffice. This concept applies to the medical field as well. A fundamental knowledge of biological systems is needed in order to design a robot to do medical tasks. Because the newer robots are more accurate and contain sensing systems that provide them with safety features, robotic systems promise to have a significant effect on the medical field. There are now pilot programs in laboratory automation, rehabilitation engineering, and neural and orthopaedic surgery.

The acceptance of robots in health care has been slowed by safety concerns. Intimate interaction between robotic systems and patients in medical environments is hazardous because virtually all commercial robots are controlled in an open loop manner and cannot themselves detect collisions with the environment, patient, or medical attendants. A recent article by Patrick Finlay [3] discusses the need and possible applications of robots in the medical field. A study conducted by Fulmer Research, a subdivision of Fulmer Systems Ltd., and headed by Finlay has identified over 400 medical robotics applications. However, details of these systems are difficult to find because they are published in diverse journals. In fact, many reports exist only as conference proceedings. This method of publication may be due to the fact that many of these systems currently lack safety features and progress toward implementation is very slow.

The application of robotic systems in health care has been approached from many different directions. It is not our intent to identify every medical robotic system in existence. Rather, our efforts will be focused on presenting robotic systems employed in the laboratory, in rehabilitation, and in surgery. The intent of this review is to point out some of the areas in medicine where robotic systems are currently being used. Because many of these systems do not provide published technical information, their review, of necessity, is brief. However, it is hoped that the short discussion of these programs will furnish the reader with enough resources to provide a starting place for new research projects. This review classifies robotic systems into three groups: laboratory robots, rehabilitation robotic systems (including sensor systems), and surgical robotic systems.

Laboratory Robots

Because many complex and time consuming laboratory procedures are still performed manually, requiring the attention of highly skilled personnel, a way to automate these procedures is sought so that skilled labor is used in an optimal fashion. In fact, since the working environment of a laboratory is very structured, applying robotic systems in the laboratory is a much simpler task than designing them for use in an operating room. Automation of laboratory procedures is growing because of the increased precision of the newest generation of robots. This precision provides the lab technician with a tool that can be used to perform tasks that demand accurate positioning.

The advantages of using a robot system over manual procedures in the laboratory to prepare samples are improved accuracy, increased sample throughput, and the capability to improve data management and task standardization. Many of the manual procedures use machines that can perform one task, but cannot be programmed to do anything else. Robot systems are more flexible and can be reprogrammed to perform a number of tasks. Thus, the robotic system is more versatile and cost effective. The employment of such a flexible system can eliminate human fatigue as well as safety precautions that are required during the use of manual machines.

There are a number of reasons, all of which are task dependent, for not automating a laboratory. Some of these problems are due to the need for flexibility, setup and programming difficulties of new robots, slow speeds of operations, and the need for using disposable supplies. Most of these hurdles will be overcome as computing speed increases, sensors become more advanced, and robot synthesis improves.

In short, laboratory robots provide the flexible automation required to meet the changing needs typical of industrial and research laboratories [4]. A review of the Sixth International Symposium on Laboratory Robotics (ISLR) discusses the needs, advantages, and payoffs that laboratory robots can offer to hospitals, industry, and government [5]. A few examples of laboratory robot systems are discussed below.

Sample preparation is the procedure of extracting a substance from the matrix in which it naturally occurs. This procedure usually requires the addition of reagents, followed by washing and extracting. Currently, a number of highly automated devices exist that incorporate sample preparation for performing routine clinical tests to determine such blood constituents as glucose, urea nitrogen, and electrolytes. Still, there exist procedures that need to be performed hundreds of times daily, such as the test for hepatitis, which require manual preparation. Three

1. Minimover-5 Robot Sample Preparation System (courtesy of Microbot, Menlo Park, CA).

different types of robot systems are being used to automate sample preparation to perform tests which, so far, have required manual preparation [6]. They are the Minimover-5 (Microbot, CA, Fig. 1) [7]; the PUMA robot sample system (Unimation, Inc., Danbury, CT) [8]; and the Zymate Laboratory Automation System (Zymark Corp., Hopkinton, MA, Fig. 2) [9].

To understand better the capabilities of a laboratory robot, consider a typical Zymark system. This system consists of a controller, a four degree of freedom (DOF) robotic arm with cylindrical geometry (the fourth degree of freedom (wrist roll) is required for pouring), and one or more workstations. The work volume is approximately 60 cm in radius and 55 cm high. Positional accuracy (accuracy at subsequent movements from a reference position) of the robot is 2.5 mm in the worst case and the repeatability (movement to a reference position a repeated number of times) is about 1 mm. The arm can lift up to 1.5 Kg and serves as a host for numerous end-effectors. End-effectors can be changed automatically to allow the robot to manipulate different containers. These end-effectors, or "hands," are located in the workstation and can be removed and replaced by the robot itself. Existing hands include a general purpose gripper, a syringe mount, and a clamping hand that allows for the attachment of probes and cannulas. Power and feedback connections allow up to two DOF for each hand.

In North Carolina, a lab robot (a modified Tecan Robotic Sample Processor (Model 505), Tecan U.S. Ltd., Chapel Hill, NC) is being used to culture and harvest bone marrow, lymph nodes, peripheral blood, fibroblasts, and solid tumors in situ [10]. The robot is controlled by an IBM PC computer. It has been programmed to drop solution into 104 petri dishes. A timing study indicated that the robotic harvester could save several hours of technologist time per day, depending on how many specimens are harvested. The study showed that the use of robotics in sample preparation can be more consistent, efficient, and economic than present day manual techniques.

Rehabilitation Robots

Presently, the area in health care with the greatest use of robots is rehabilitation. Rehabilitation is the restoration of normal form and function after injury or illness, and rehabilitation engineering is dedicated to providing assistive equipment for the disabled. There are many reviews of robotic systems used in rehabilitation [11,12]. The areas that will be covered in this section are tactile sensors, assistive devices for the blind, prosthetics, and orthotics. These are the areas of major research for robotic systems in rehabilitation and are provided because we would like to emphasize the diversity in the medical field.

Handicapped individuals require personal attention and care. These people rely on family members or attendants for their daily needs and for mobility. The largest cost confronting these individuals is not medical care but maintenance; attendant care, nursing home and home care expenses, the loss of productivity because of the inability to work, and the lost wages of family members who have to take time off from their jobs in order to help. Assistive devices offer the handicapped person the chance to decrease these costs as well as to function more efficiently in society. Some robot systems are being developed to help the handicapped with these problems (e.g., a modified HERO 2000 mobile robot [13]), but many of these systems cannot make it to the market because of high costs and low demand. The modified HERO 2000 robot is a low cost system composed of commercially available components, which is controlled through a user interface developed on a Macintosh computer. It is interesting to note that in 1980, over three thousand times as much money was spent on people and equipment who cared for the disabled than was spent on research and development related to technology that would allow the disabled to care for themselves ($210 billion versus $66 million) [14]. Money spent on research and development of assistive devices is economically beneficial to society ($1.00 spent on research and development returns $11.00 in cost benefit to society) [15]. These reports help support the need for research in rehabilitation engineering.

Tactile Sensors

The field of medical robotics has contributed greatly to the area of sensor design. Many of today's industrial robots are using sensors that were designed for use in prosthetic and orthotic devices. Tactile sensing is an area that will benefit industry as well as medicine. Tactile sensors that are used in prosthetics and orthotics are also being used in many industry tasks (such as grinding, deburring, and welding). These sensors usually incorporate an array of force transducers (temperature sensors are used, too) into an artificial skin and can therefore provide three- dimensional information about an object to the robot operating system. A survey of general purpose manipulation aids, which also discusses the importance of tactile sensing techniques, can be found in Grupen, et al. [16].

Force sensing is important in medical applications because the robot must interact with objects and people in the environment. Objects that require manipulation are usually delicate and fragile, and must be handled with care. Another important reason for using force sensors is to avoid problems that occur when the robot motors are overloaded. Force sensors can be used to help protect both the user and the robot system. Many of today's workstations for the handicapped have robot arms that require a force sensor to grip objects.

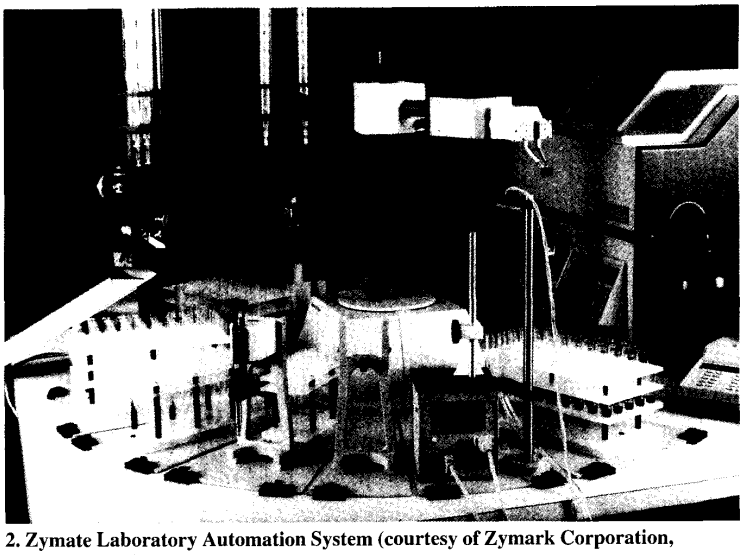
A tactile skin (also known as tactile imaging skin since it provides three-dimensional information) would enable a

robot to grasp and manipulate objects that are slippery, geometrically complex in shape, or fragile. One type of skin is based on magnetoresistive technology [17]. In this design, the skin consists of a thin-film magnetoresistive array with sensor elements 2.5 mm apart, covered by a sheet of rubber and a row of flat wires etched on Mylar film. A more compact spacing of sensor elements can make it twice as sensitive as the tactile discrimination capability of a human (0.5 mm). By varying rubber thickness and stiffness, the sensors resolution and range can be adjusted. This type of sensor can give three-dimensional data to a controller (area and force), thus providing the robot with a three-dimensional tactile recognition capability.

A tactile sensor and a thermal sensor have been designed for the Utah-MIT dextrous four-finger hand (Fig. 3) [18]. The tactile sensor utilizes capacitive transduction based entirely on silicone elastomers, and the thermal sensor measures heat conductivity by radiating heat to an object and measuring the resulting temperature variation. This device is the best presently available for mimicking the performance of the human hand. However, further refinements are necessary before it can be used as a prosthetic device.

Another interesting robot that utilizes sensors is under development at the Pacific Northwest Laboratory. This is a robot mannequin with movement in 38 degrees of freedom that is being developed in order to test the effectiveness of protective clothing in hazardous environments [19]. By simulating human movements and positions, the mannequin will be able to test protective clothing in a realistic workplace environment. Special skin sensors will detect penetration of the protective clothing by the hostile environment. The mannequin can replicate the following ancillary systems: breathing, perspiring, skin heating, and sampling (via skin sensors) of chemical reagents. These artificial systems would be useful for disabled persons who have lost the sense of touch.

Tactile sensors offer a robot many feedback advantages that can be used with other sensors, as well as with end-effector control. Because of the quantity of literature in this area, only a few articles are reported. The design of tactile sensors for guided exploration and shape perception is discussed by Hemani [20]. Many new designs for force transduction have also come about due to the increased interest in tactile sensing, such as a miniature electrooptical force transducer that can be embedded into the sole of a shoe as a means to measure foot impact forces [21]. There have also been attempts to design a synthetic skin for robots, which could house numerous sensors for thermal, force, and touch reception [22].



2. Zymate Laboratory Automation System (courtesy of Zymark Corporation, Hopkinton, MA).

Assistive Devices for the Blind

Robotic systems and sensing devices are also being used as aids for the blind. These are a special subset of medical robots, as they are concerned with sensing rather than physical motion. For example, NASA is developing a device that may improve the vision of more than a million Americans who suffer from so-called low vision, which cannot be corrected medically, surgically, or with eyeglasses. The low vision enhancement system employs digital image processing technology that was developed to enhance pictures of the moon and Mars. The device will resemble mirrored wraparound sunglasses [23]. Research in this area may also help with visually guided robot systems.

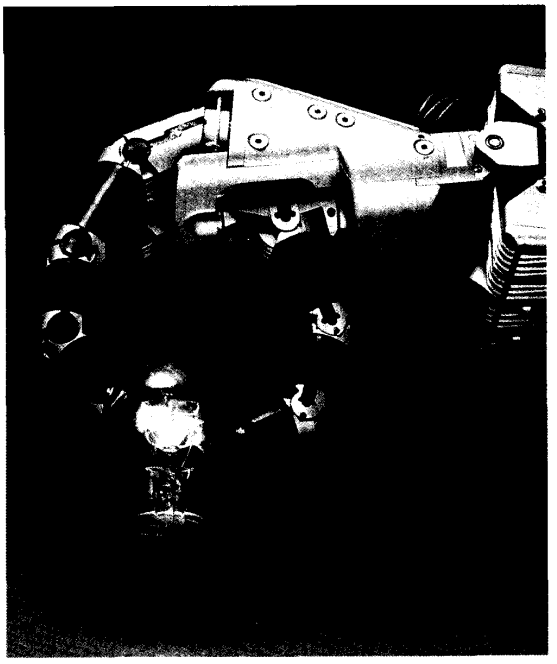
The newest generation mobile robot is helping the blind with the problem of navigation (Fig. 4). In the past, most such devices were built as local mobility aids for the blind, i.e., the device was intended to sense obstacles in the traveler's immediate path. The more global problem of absolute orientation and navigation is just now being addressed. A good review of mobility aids and orientation aids can be found in Brabyn [24]. One of the most recent robotic aids for the blind that can address the issue of mobility and orientation is the Japanese MELDOG project [25]. This robot is designed to replicate the functions of a guide dog. It can be programmed with "landmark" information from a city and has the capability to guide its owner to a desired destination. Feedback information is relayed to the user by special sensor stimulation methods.

Prosthetics and Orthotics

Prosthetic and orthotic devices are similar in concept but differ in function. A prosthesis is designed to take the place of an anatomical part, i.e., an artificial limb, or an artificial organ [26]. Although prostheses have been around for a long time, not until after World War II did scientists and engineers become firmly committed to their development. An orthosis, on the other hand, is an external device that can support, position, or protect a limb, trunk, neck, or any other body part [26]. Wheelchairs and exoskeletons [27] are examples of orthoses. The types and designs of wheelchairs is discussed by Warren [28] and McLaurin [29].

Much more work is necessary before a prosthetic device can replace a human limb. The human upper arm contains 87 external mechanical degrees-of-freedom [30], whereas most prosthetics have 4 to 7 DOF. Still, current systems can provide good functional replacement when a limb is lost. An informative review of upper extremity prosthetics that deals with design and the types of medical problems that must be overcome can be found in Murphy, et al., [31].

Many prosthetic devices are classified by the type of control they use. There are two main types of control: body and external. Body control utilizes a harness that is attached to the body and can be tightened by moving functional parts of the body. Tightening and loosening of the harness provides the control for the prosthetic device. External control utilizes switches that can be activated by body movement or generated potential (e.g., muscle potentials) [32,33]. Since feedback to the user of a prosthesis is vital to proper functioning, it seems logical to design a prosthesis that would use myoelectric signals for input and produce a neural stimulation for output. This design



3. The Utah-MIT dextrous four finger hand (courtesy of S.C. Jacobsen, University of Utah, Salt Lake City, UT).

4. MITI of Japan's seeing-eye robot dog, MELDOG.

would ensure a tight feedback loop. The most enlightening paper on this subject, which gives extensive details of the mechanical design, human factors, and costs of an upper extremity prosthesis, is by Jacobsen, et al., (Fig. 5) [30].

Rehab - Manipulators

A rehabilitative robotic manipulator, termed a rehab-manipulator, is not designed to perform repetitive tasks like its industrial counterpart; instead, it must be able to perform various tasks in minimally-structured environments. Most of these manipulators are being designed along with computer workstations so that disabled people can function more independently (Figs. 6 and 7). These devices can help a disabled individual with important everyday tasks such as eating, answering the phone, and using a personal computer (as a means of livelihood). Many rehab-manipulators have been built, tested, and evaluated, but because of their high costs they are not available commercially. However, with decreasing computing, mechanical, and electronic costs, rehab-manipulators appear to have a bright future. The most noteworthy are the Johns Hopkins Robotic Arm/Work Table [34-36], the Spartacus Project, which uses a nuclear-industry master/slave manipulator [37], and the Stanford Robotic Workstation [38]. These systems are very creative and future research may give better insight into the intimate interactions of robotics, as both an aid and a tool for people.

Assistive Robotic Systems in Rehabilitation

At Santa Clara University in California, a methodology has been formulated whereby two planar robot arms are used to aid in both postoperative rehabilitation of joints following surgery and estimation of body segment parameters [39]. It has been shown that to regain good range of motion following joint surgery, a physical therapy regime utilizing continuous passive motion (CPM) is needed. This treatment following joint surgery has been shown to be useful in helping to regain range of motion, reduce stiffness, reduce the need for medication, and reduce the length of hospital stay. Current CPM machines exist and are used by the clinical community, but they are inflexible, non-reprogrammable, and are mostly designed for planar motion. Their present design assumes that human joints are ideal and have fixed axes of motion, which is a poor assumption. Also, they require a lengthy setup time and do not use feedback control techniques, which makes them less robust then their robotic counterparts. A robot CPM machine could be setup to move the limb in a nonplanar as well as planar fashion, allowing for the creation of new rehabilitative techniques.

The robot arms are equipped with force sensors at their wrists, as well as force plates at their bases. The force sensor data can be used for trajectory control or as input into body segment parameter equations that can provide information such as mass, center of mass, and joint reaction force of different parts of the body. Joint reaction force is important in the design of prosthetic and orthotic devices, and for other applications in rehabilitation and sports medicine.

To use the robot system for CPM therapy, a physical therapist will guide the robot arms through an appropriate trajectory path in a manner similar to that used by current paint spraying and welding systems ("on-line" training). During this "teaching" phase, the trajectory is recorded along with the reaction forces. The force data gathered during a therapy regime can then be used to evaluate a patient's progress and to assess the effectiveness of the CPM methodology. The two-link robotic system designed for this study has a system response that will move from one equilibrium state to another in about one second.

The University of Pisa is currently exploring expert robotic systems that are capable of executing complex sensory-motor sequences aimed at gathering data useful for diagnostic purposes [40]. With the rising cost in medical care, and the difficulty in finding attendants to assist disabled people, the opportunity of using robots to perform simple health care related tasks must be seriously considered. One part of these tasks is the periodic evaluation of the physical condition of a patient by means of palpation procedures (i.e., feeling for arterial pulse, sensing of body temperature, measuring the chemical composition of sweat, or detecting nodules in soft tissue such as breast and/or internal abdominal organs). There are two main problems associated with a robotic palpation system. The first has to do with finding an appropriate sensor-based control strategy, and the second is concerned with creating an "intelligent"

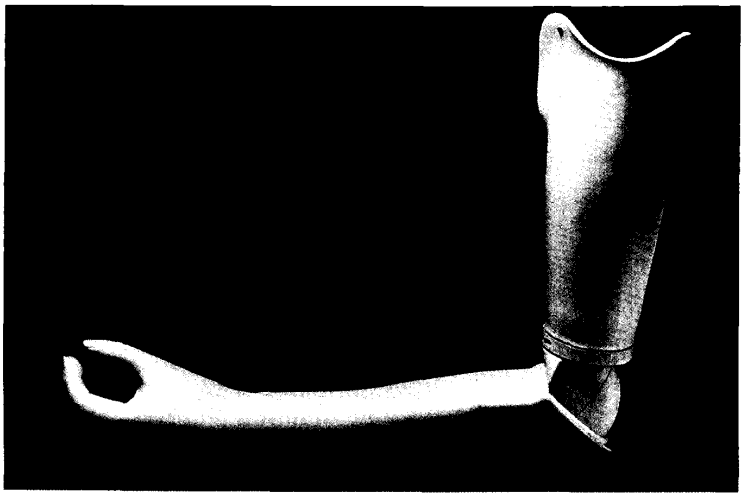
control algorithm that can manage different perceptual procedures.

In order to answer some of the control strategy problems, a simple one-finger robot system has been designed to search and acquire the radial pulse at the wrist by palpation. The finger is made up of four rigid links connected by hinge joints. Exteroceptive data are sensed by the fingertip tactile sensor, which has an anthropomorphic configuration. The sensor is composed of three layers, a dermal layer (with 128 sensing sites), a rubber layer, and an epidermal layer (with 7 sensing sites). Both dermal layers are made of ferroelectric polymer (polyvinylidene flouride or PVF_2). The dermal layer senses fine spatial details, whereas the epidermal layer senses coarse spatial details. The rubber layer is used to provide compliance and to shield the dermal layer from temperature fluctuations. Because the epidermal sensor responds primarily to indentation (i.e., strain), and the dermal sensor primarily measures stress, both sensors can be used together to provide a measure of "hardness." This is an important characteristic in the palpation of the breast or abdomen.

To provide pulse data, the robot system must fixate the wrist of the subject, or information must be provided to the robot system about the whereabouts of the wrist. The fingertip of the robot would then begin pressing the wrist of the subject in a highly controlled manner, using signals from the dermal sensors as feedback. A high-level expert system is used to evaluate the pulse waveform and to send appropriate commands to the low-level controller in charge of moving the fingertip. The robot used in this study was capable of extracting pulse waveforms from the wrist. However, the sensitivity and the spatial resolution of the dermal sensor array was rather low, and some inaccuracy in the position control of the finger due to backlash and frictional effects was present. Solutions to these problems are being pursued. To help with the sensitivity of the sensor, a contact-resolving sensor is being made that is capable of detecting the resultant force/torque vector with virtually infinite resolution. Position control of the fingertip will be aided by miniature encoders placed in the finger joints. The robot system shows that a multilevel control hierarchy is beneficial in designs for medical assistance.

Surgical Robots

Industrial robots are just beginning to be used in the operating room. Two classes of robot systems can be defined in this area: robots that assist the surgeon in the surgery, and robots that actually perform the surgery. The following discussion comprises a list of robotic systems that are being used for surgery. This list is not comprehensive, but instead serves to demonstrate the versatility of a robot in providing aid to the surgeon.



5. The Utah artificial arm (courtesy of S.C. Jacobsen, University of Utah, Salt Lake City, UT).

Surgical Assistive Robots

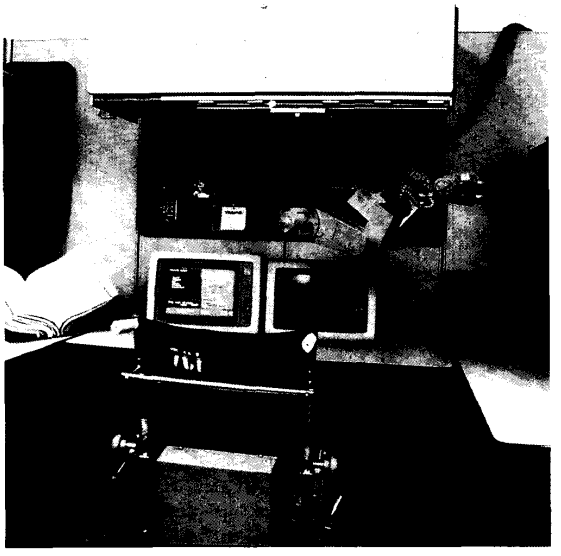
Stereotactic neurosurgery is a technique for guiding a delicate instrument into the brain through a small holed drilled in the skull, without direct visualization of the surgical site. Minimizing brain damage by avoiding vital parts of the brain, such as major blood vessels and motor centers, is crucial and the best way to do so is to ensure that the instrument travels in a straight-line path [41]. This pathway is attained by inserting the instrument through a guide that is fixed to a stereotactic frame which attaches to the patient's skull. This device allows the guide to be positioned along any prescribed trajectory by means of a system of angular settings, scales, and verniers. The only remaining problem for the surgeon is to establish the location of the surgical site.

To overcome this problem, a CT-guided stereotactic head frame was developed at the Memorial Medical Center in Long Beach, California. The patient's skull is fixated to the frame, and three N-shaped locators are used to reference the scan plane with respect to the frame coordinates, to allow any point in the CT picture to be found in three dimensions with respect to the frame coordinate system. This procedure was clinically used from 1980 to 1984; however, the manual reading and setting of the frame parameters is tediously slow and prone to error.

Through the use of a high precision robot arm (PUMA 200), this procedure was automated. A PUMA robot was interfaced to a CT scanner (Siemens DRH) and fitted with an instrument guide at its end-effector (Fig. 8). Because the PUMA 200 robot has a relative accuracy (or repeatability) of 0.05 mm, a calibration procedure was devised that could compensate for the inherent robot error so that submillimeter accuracy could be attained [42]. The calibration procedure uses a high-precision grid table and a high-precision object that can be located at different sites on the table. The robot end-effector is equipped with a tool that is to be mated with the object on the table in order to provide accurate measurements. A five-fold increase in accuracy was obtained after performing the robot calibration procedures. This accuracy is very important as submillimeter positioning is necessary for this type of surgery.

The experimental procedure begins by acquiring CT data from a patient with the stereotactic head frame in place. The patient, along with the robot (which is bolted to a pedestal), is wheeled into the operating room and the pedestal is clamped to the operating table. The target coordinates are then located in the robot's reference frame and the robot is programmed to point the guide exactly towards the target. The surgeon can then maneuver the robot arm into a variety of positions, while the guide remains pointing at the target site. A series of tests using a watermelon which contained a small lead BB (simulating a lesion) were conducted prior to the first human experiment. In April of 1985, a brain biopsy was taken from a 52-year-old man using the robot system. A positive biopsy was confirmed on the first sample.

At Grenoble University Hospital in France, another computer driven robot is



6. The Stanford robotic workstation (courtesy of M. Van der Loos, Stnaford University, Stanford, CA).

7. Johns Hopkins robot arm/ worktable (courtesy of W. Seamone, Fleet Systems Dept., Applied Physics Lab, Johns Hopkins Rd., Laurel, MD).

being used for stereotactic surgery [43]. The system incorporates CT data as well as magnetic resonance information to direct a robot to the target site. The system is composed of a VAX 11/780 computer, a Thomson CGR Magniscan 5000 magnetic resonance imager, a VINIX (Digital Design) processing device for reconstruction of the lesions and image processing, and an AID Universal robot controlled by an AT computer.

Aside from helping with the actual surgical procedure, robots can also be used to assist the surgeon by holding, clamping, or manipulating a limb [44]. A patient--manipulating robot, called Arthobot, was developed and tested at the University of British Columbia Health Sciences Hospital in Vancouver, Canada. This robot can be directed through a control panel or by voice command (20 commands have been pre-programmed). The robot is useful during surgery when a patient's limb must be held at a particular distance and orientation from the body for a long duration (e.g., pelvic surgery). Physician attendants do not possess the endurance that the robot system can provide and therefore unwanted movements of the limb can be introduced into the surgical operation. The robot has assisted in more than 200 clinical operations.

A passive robot (in vivo spinal kinematic instrument, or SKI) has been developed by Oklahoma State University to evaluate surgical correction of the scoliotic spine while in the operating room [45]. In the past, x-ray techniques have been used to confirm the presence of scoliosis; however radiographs do not provide a complete description of the scoliotic spine. To surgically correct the spine, it is necessary to obtain a complete 3-D discription while the patient is still on the surgical table. An instrument was developed that consists of six moving rigid links connected by six pin-joints whose relative motion is monitored by high resolution rotary potentiometers. The instrument has an accuracy of 0.3 degrees in rotation and 0.5 mm in translation. Only point location is measured by the end-effector and therefore three of the six degrees of freedom are redundant. The redundancy permits a user to manipulate the instrument into some of the more inaccessible locations in the human spine, both before and after surgical manipulation.

The SKI is mounted to a fixed base within easy reach of the patient's spinal column. Four points are chosen to erect a reference frame. Three are located on the sacral joint and the fourth is located at T1 of the spinal column. To locate the position and orientation of each of the vertebrae with respect to the sacral reference coordinate system, four points are collected from distinctive locations on each vertebrae. The curvature of the spine can then be obtained by connecting the centroids of each vertebrae with a three dimensional cubic spline curve. This curve can be used to judge different corrective techniques in the hope of optimizing the surgical procedure.

In order to increase the efficiency of the surgeon in an operating room, the use of a robot for instrumentation positioning and holding, which requires sensing the surgeon's next action by monitoring head movement or voice commands, is being developed at the Robotics Institute at Carnegie Mellon University [46]. The use of a robot for these tasks should help reduce the exertion and duration of operative procedures. To demonstrate the potential of a robot performing these kinds of tasks, a Merlin 6-DOF robot is used to hold a surgical microscope. It is estimated that these microscopes are currently used in about 20 percent of surgical procedures. These microscopes are awkward and require either manual readjustment, voice control, or the use of foot pedals to command individual axis motions. Such control makes complex orientations difficult to obtain (and maintain). A new approach is to continuously sense the surgeon's head position and orientation, and to reposition the microscope accordingly. A low-frequency magnetic sensor is used to obtain head position, while an IBM PC AT acts as a controller. High speed communication between the computer and the robot is accomplished through the use of dual-ported shared memory, instead of a serial link.

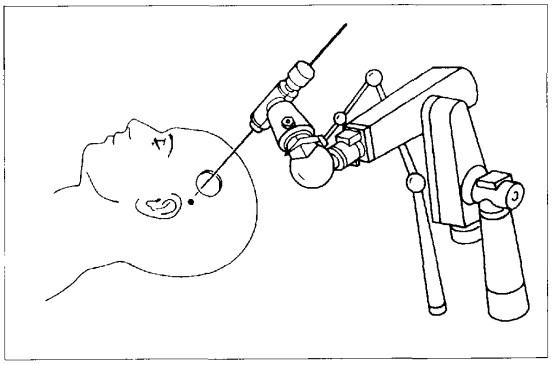
Calculation of the appropriate micro-

scope location is done by assigning cartesian frames to points on the microscope and to points on the user's head, and then performing the necessary transformations from one frame to the other. The current software allows for three modes of operation: 1) tracking, whereby the microscope imitates head orientation at a desired fixed distance from the eyes as the surgeon scans an area; 2) pivoting, in which the microscope pivots about a fixed focus as the surgeon seeks different views of the operating site; and 3) cartesian, which allows for fine adjustments. These modes are invoked under voice control to provide the surgeon with maximum freedom of motion. In case of power failure or when given an emergency command, a clutch-brake system prevents the robot from moving.

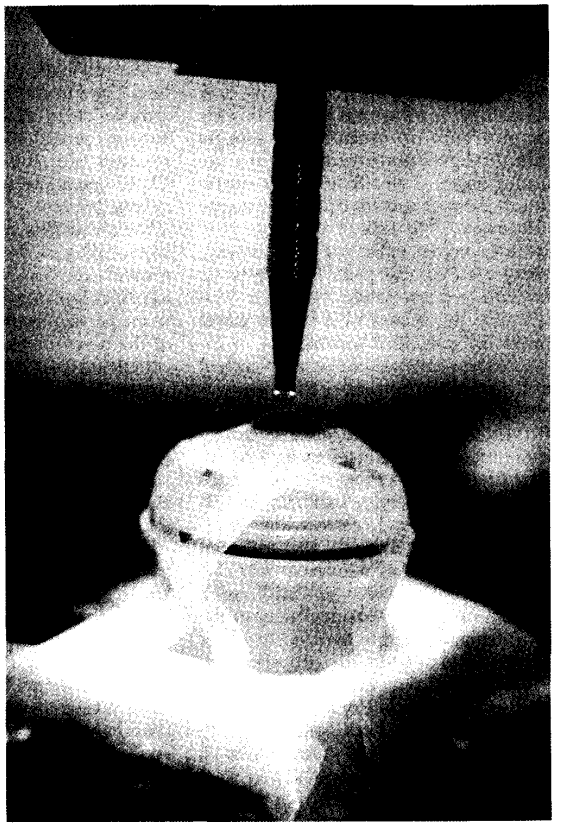
Two low-risk techniques to diagnose fetal abnormalities are amniocentesis and chorion villa biopsy. The latter method appears more promising because it can be performed at twelve weeks gestation, allowing early action to be taken if required. The procedure involves the insertion of a biopsy needle through the abdominal wall, and then penetration of the uterus, which must be done with a stabbing action due to the elasticity of the uterine wall. During these procedures, the position of the embryo is determined by ultrasound imaging, similar to normal pregnancy ultrasonic scans. Skill is needed to perform the stabbing maneuver, and early investigations at Huddersfield Polytechnic in the United Kingdom have shown that a PUMA 560 robot may be able to perform the task with a high degree of repeatability and reliability [47]. However, a problem existed with the implementation of the robot in this operation. The radiographer could not apply enough pressure on the ultrasound transducer to pick up relevant information. Because of this complication, it was agreed that the robot be used as a clamp in order to hold the transducer on the abdominal wall, and thus provide the surgeon with a stable platform from which to perform a biopsy stab. A gripper was designed to both hold the ultrasound transducer and serve as a guide for the biopsy needle. No clinical trials have yet been reported. The attempted procedures and knowledge gained here are beneficial in regard to experience with the use of robots in the operating room.

Clinical trails of a pre-robotic retraction system have been conducted at the Vancouver General Hospital and at the University of British Columbia in Vancouver [48]. Retraction techniques can create problems for a patient, such as lacerated tissues or restricted blood flow, which can result in ischemia and devitalization of wound edges that can affect healing. Currently, there are two ways to support and position a retraction blade; through the use of a surgical assistant or by the use of a mechanical retraction device. Using surgical assistants is not cost effective and many problems are encountered, such as imprecise positioning, human fatigue, and lack of feedback of applied tissue pressure. Most mechanical retraction devices have time-consuming adjustments and lack strength as well as force feedback. Because of these problems, a robotic system to perform retraction was developed.

The objectives of the research were to develop and evaluate a pre-robotic positioning system for retraction that would replace and improve upon the manual techniques that are commonly used, and to add advanced automated accessories to regulate retraction force or position. The pre-robotic retraction system is lightweight, pneumatically powered, and has an electronically controlled positioner. Ball joints are used to connect three shafts and provide a spherical geometry with redundant position capability. Safety features include an alarm warning when pressure drops, and provision to lock the arm in place when pneumatic or electric power is lost. Twenty clinical trials have



8. CT-gudied sterotactic brain surgery (courtesy of Y.S. Kwoh, Dept. of Radiology, Memorial Medical Center, Long Beach, CA).



9. Robotic radial keratotomy (courtesy of S. Levy, Norwalk, CT).

been completed (mostly arthoplasties of the knee and the hip) since January, 1989. All of these trials were considered very successful. The major problem with the system, and one that will plague all robot surgery systems, is the issue of sterility. Protective sterile drapes or gas sterilization appear to be the only methods currently available to such systems. These methods are limiting factors when one considers the automation of surgical procedures.

Surgical Robots

A PUMA 500 robot is being developed to perform radial keratotomy, a form of refractive opthalmic surgery for the correction of myopia (Fig. 9) [49]. Although improvement is found after surgery, scatter from the desired refractive correction, with drift continuing up to several years following the procedure, has occurred. It is thought that through improvements in the accuracy and reproducibility of the operation, these post-operative problems can be eliminated. The task of the robot is to score the cornea of the eye while moving along a curvilinear path. Eight cuts are needed, which when finished will resemble the spokes of a wagon wheel (eight-incision radial keratotomy).

A Pilling diamond knife set at 95 percent of the average paracentral thickness was mounted onto the end-effector of the PUMA robot, and a curvilinear cutting path program was created using VAL II. Experiments were performed on human globes that were injected with air through the optic nerve and sealed with "superglue." Incision linearity was excellent and the angle between incisions was also very good. Difficulty in maintaining penetration depth was attributed to the tool clamp, and not to the inadequacy of using a robot system.

Although a robot was not used in this procedure, the novelty of the method warrants attention. A robotic controlled scanning handpiece has been used to aim an argon laser in the treatment of port wine stains (PWS) [50]. Argon photocoagulation of PWS is a very tedious, time consuming, and highly skilled procedure, which often has poor reproducibility. The laser treatment is achieved by thermal coagulation of the abnormal blood vessels in the upper part of the dermis. Heat conduction from the superficial dermis to the deeper part of the dermis must be avoided or scarring will occur. A handpiece with a scanning mechanism and microprocessor control can provide an easy, fast, homogeneous, and reproducible blanching of the skin where the PWS resides, with a lower risk of scarring. Because of the scanning procedure, local anesthesia is not required, and results are more reproducible from one physician to another. Over a period of 11 months, 123 outpatients were treated with the "robotized" scanning device. The treatment duration was reduced using the robotized scanning device in comparison to the more favored manual procedures.

Presently, the Centre for Robotics at the Imperial College of Science, Technology and Medicine in London is using a modified PUMA robot to perform prostatectomies [51]. It is estimated that one out of every ten forty year old men has a chance of undergoing transurethral resection of the prostate (TURP), which relieves urinary outflow obstruction secondary to prostatic enlargement. This operation is second to cataract extraction as the most costly major operation under Medicare. The procedure utilizes a resectoscope that is inserted in the urethra. A tungsten wire loop can then be manipulated in order to remove "chips" of the prostate. In order to become proficient with the procedure, residents are required to perform more TURP operations than any other urological operation.

The viability of the concept was shown by modeling the procedure with the use of a simulated penis, which was attached to a perspex box into which a potato (serving as the prostate) was rigidly fixed. The use of the robot enabled the operation to be completed in five minutes, which is a vast improvement from the manual technique, which usually takes about an hour. Clinical TURP data on six patients was presented. None of the patients showed signs of intra-operative or post-operative complications and all were discharged by the third post-operative day.

Experiments involving the use of a robot in total knee arthoplasty were done at the University of Washington in Seattle [52,53]. It was thought that the procedural methods for total knee arthoplasty could be improved if there were a way to reproduce smooth bone cuts that were an exact press-fit to the component, and in proper alignment with respect to bone and soft tissue. The use of jig systems and hand-held instruments makes accomplishing these goals difficult. By introducing a robot system to the operation, it was thought that improvements could be made to the existing surgical techniques.

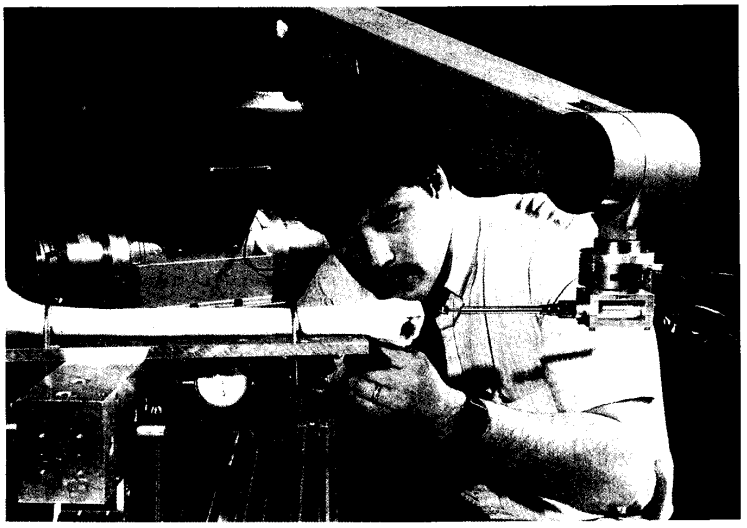
The process consists of three phases: 1) planning, 2) orientation, and 3) cut generation. In the planning phase, the femur--prosthesis positional relationship is established; in the orientation phase, the location of the femur within the work volume of the robot and the subsequent location of all the necessary cuts is established. Finally, the cut generation phase produces the bone cuts that allow the prosthesis to be mounted onto the femur. In order to locate the position of the cutting planes and the bearing surfaces relative to the bone anatomy, a 3-D model of the digitized surface anatomy of the femur is made. This allows the surgeons to inspect the cut planes from any orientation, and provides them with the capability to iteratively adjust the position of the cut planes if necessary.

A plastic femur was attached to the base of a 5-DOF industrial robot in such a manner that conventional surgical approaches would not be obstructed, allowing experimental data to be obtained. An air-powered milling tool attached to the wrist of the robot was used to perform the cuts. The robot was capable of positioning the tool with an accuracy of 0.2 mm in translation and 0.09 degrees in orientation. Assessment of the error associated with the procedure showed that most of the error resulted from tool chatter, poor blueprints that were used to define the cut planes, and poor reproducibility in locating anatomical markings. The resultant cuts were very smooth and allowed the placement of the prosthetic component on the femur to within 0.51 mm in translation and 0.64 degrees in rotation. This procedure showed that through the use of a robot, a surgical procedure could be performed with far more precision and accuracy than by conventional methods.

Most recently, a robot surgery project at the University of California, Davis in collaboration with IBM corporation is under way that will aid orthopaedic surgeons in custom hip replacement operations (Fig. 10) [54,55]. A modified SCARA robot with 5-DOF at the end-effector will be used. In order to perform the cutting and calibration procedures, a pneumatically powered Anspach drill will be attached to the end-effector along with a 6-DOF force sensor, which will monitor the force placed on the drill tip. A vision system will be used to help ensure that the bone milling operation is safe.

Arthoplasty, the surgical replacement of joints, has revolutionized the treatment of crippling diseases such as osteoarthritis and rheumatoid arthritis. This procedure benefits both older and younger patients who suffer from congenital, traumatic, or developmental disorders of the joint. In the early sixties, the procedure was pioneered by Sir John Charnley, who was one of the first surgeons to use polymethylmethacrylate bone cement in order to stabilize the prosthesis in the bone. Unfortunately, many implants which use this cement must be replaced after a few years due to loosening and cracking of the bone-cement interface, which causes pain and instability.

A promising alternative is the use of a cementless implant. This implant contains areas on its surface made of a fine mesh of titanium wires, which creates a connected porous surface into which bone can grow, stabilizing the implant. The advantage of using an implant that incorporates bone



10. Robotic total hip replacement (courtesy of B. Mittelstadt, University of California, Davis, CA).

ingrowth lies in the fact that the stresses applied along the implant are minimized. Stress reduction occurs because where stresses are greatest, the most bone forms, eventually distributing transmitted loads over a very large surface area. The bone implant interface can remodel or adjust to changing stress conditions for an indefinite period, minimizing implant loosening. Clinically, however, the results are not always good. Poorly designed implants, imprecise surgical methods, and anatomic variations often lead to poor implant seating and movement between the implant surface and the surrounding bone, which inhibit bone ingrowth.

The biggest problem concerning this procedure is accurate placement of the implant into the bone. A tight fit (minimal gap distance) is needed in order for the bone to grow into the implant. Currently, this operation is done using a broaching tool, similar to a chisel, and a mallet. A surgeon "eyeballs" where to cut out the bone with the help of x-ray scans and special clamping devices. Many surgeons today use custom implants that are designed and manufactured from 3-D models created by CT scan data. Such custom design is assumed to improve the fit of the implant to the bone and therefore increase the success rate of the operation, but few empirical studies support this hypothesis. The technology of cutting and shaping the bone has not kept pace with the technology of manufacturing the prosthesis, and consequently an opportunity exists to improve the procedure.

Through the use of robotics, the bone cavity can be made to match the surface geometry of the custom implant more accurately. This improved fit should result in better bone ingrowth and increase the lifetime of the implant. In order for a robot system to assist in surgery it must be capable of several tasks. For instance, the robot must be able to locate accurately the position and orientation of the site of surgery. This can be done by placing markers prior to the surgery and storing a set of CT scanned images. During surgery, the robot would find these markers and correlate its position with the CT scan data. This match provides a starting position and orientation for the robot. It could then cut out a predetermined cavity, which would have a center of axis coincident with that of the femur (or any axis so desired).

Conclusion

Robots have the potential for enormous benefit to the medical field, but researchers must proceed with care to ensure human safety. Medical robots must be outfitted with appropriate sensor systems so that no harm can come to anyone in contact with the system. With the rising cost of medicine, automation may be one way to make medicine more affordable. Simple and reliable ways must be developed to calibrate a robot so that optimal performance can be achieved easily. Review papers on this subject have been published; most notable are Hollerbach [56] and Roth, et al., [57].

One area not covered in this review is the use of robots in medical education. A robot system has been developed to facilitate learning in very young disabled children [58]. This system can provide disabled children with a more intuitive idea about robot control (from a user viewpoint), which will be very helpful to them as they grow up and possibly use such systems for their livelihood. Although many areas of medicine will benefit from robotic devices, the surgical robotic system will help reduce the cost and duration of rehabilitation by improving surgical procedures. They have the cability to make a great contribution to society in a very short period of time and therefore are currently being pursued with zeal.

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(continued on page71)

Editorial Éditorial

Robots in medicine

Robots en médecine

Robots are poised to revolutionize the practice of medicine. Artificial intelligence, miniaturization, and computer power are contributing to the rise in design and use of robots in medicine.

Medical robots had their start about 34 years ago when an industrial robot and computed tomography navigation were used to insert a probe into the brain to obtain a biopsy specimen (1). This was followed by a number of robots that were capable of certain urological procedures and total hip arthroplasty. These fully autonomous robots, however, did not find favor with surgeons and subsequent robots were designed to be slaves to surgeon masters (1).

Today, medical robots are well known for their roles in surgery, specifically the use of robots, computers and software to accurately manipulate surgical instruments through one or more small incisions for various surgical procedures (2). A 3-D high-definition magnified view of the surgical field enables the surgeon to operate with high precision and control. One instrument, da Vinci, approved by the FDA in 2000, is said to have been used to perform over 6 million surgeries, worldwide. Patient benefits from robot-assisted surgery are largely those associated with the laparoscopic approach — smaller incisions, reduced blood loss, and faster recovery. Long-term surgical outcomes don't appear to be different from those of traditional surgery and the system has occasional malfunction. Surgeons benefit from improved ergonomics and dexterity in comparison with traditional laparoscopy. Major drawbacks are high cost and the need for training of surgeons and the surgical team. The base price of a da Vinci system is upwards of $1 million.

Various companies are developing surgical robots designed for a single specific procedure such as knee or hip replacement. Other companies are seeking to build systems that incorporate artificial intelligence to assist surgical decision-making (1). In neurosurgery, Modus V is an automated robotic arm and digital microscope built by a Toronto company and based on the space shuttle Canadarm technology (3). The arm tracks surgical instruments, automatically moves to the appropriate area in

Les robots s'apprêtent à révolutionner l'exercice de la médecine. L'intelligence artificielle, la miniaturisation et la puissance informatique contribuent tous à la montée de la conception et de l'utilisation des robots en médecine.

Les robots médicaux ont fait leur début il y a 34 ans lorsqu'un robot industriel et la navigation par tomodensitométrie ont été utilisés pour insérer une sonde dans le cerveau afin d'obtenir un spécimen de biopsie (1). Cette première a été suivie de plusieurs robots capables de certaines interventions des voies urinaires et d'une arthroplastie complète de la hanche. Cependant, les chirurgiens ne privilégiaient pas ces robots entièrement autonomes et les robots subséquents ont donc été conçus pour être des esclaves aux maîtres chirurgiens (1).

Aujourd'hui, les robots médicaux sont bien connus pour leur rôle en chirurgie, plus particulièrement l'utilisation des robots, des ordinateurs et des logiciels afin de manipuler des instruments chirurgicaux avec exactitude dans une ou plusieurs petites incisions pour diverses interventions chirurgicales (2). Une vue 3-D à haute définition magnifiée du champ chirurgical permet au chirurgien d'opérer avec une grande précision et un excellent contrôle. Un instrument, da Vinci, qui a été approuvé par la FDA en 2000, aurait été utilisé pour réaliser plus de six millions de chirurgies à l'échelle mondiale. Les patients qui bénéficient de la chirurgie assistée par robot sont surtout ceux associés à l'approche laparoscopique — de petites incisions, une perte de sang réduite et un rétablissement accéléré. Les résultats chirurgicaux à long terme ne semblent pas différents de ceux de la chirurgie traditionnelle et le système a connu des ratés occasionnels. Les chirurgiens profitent aussi d'une ergonomie améliorée par rapport à la laparoscopie traditionnelle. Les principaux inconvénients sont le coût élevé et le besoin de former les chirurgiens et l'équipe chirurgicale. En outre, le prix de base d'un système da Vinci s'élève à 1 000 000 $.

Diverses compagnies développent des outils chirurgicaux conçus pour une seule intervention spécifique comme le remplacement du genou ou de la hanche. D'autres compagnies cherchent à construire des systèmes qui intègrent l'intelligence

which the surgeon is working, and projects a magnified, high resolution image on a screen.

Prostheses are benefitting considerably from new structures and control systems (2). Robotic limbs with bionic skin and neural system are allowing a remarkable degree of user control. Robotic exoskeletons (orthoses) are finding use in rehabilitation, assisting paralyzed people to walk and to correct for malformations (2). Robots are also finding a place in keeping hospitals clean as hospital rooms are being disinfected with the use of high intensity UV light applied by a robot (2).

Traditional endoscopy may soon be replaced by small robots that can be driven to specific locations to carry out various tasks such as taking a biopsy or cauterizing a bleeding blood vessel. Microrobots may be employed to travel through blood vessels and deliver therapy such as radiation or medication to a specific site. Robotic endoscopic capsules can be swallowed to patrol the digestive system, gather information, and send diagnostic information back to the operator. Then there are robotic nurses designed to assist or replace overworked nurses with tasks such as digital entries, monitoring patients, drawing blood, and moving carts. A really exciting area of medical robotics is in replacement of antibiotics. The concept is that nanorobots with receptors to which bacteria adhere can be used to attract bacteria in the blood stream or in sites of local infection.

Do any of these grand developments have a place in veterinary medicine? Robots are currently being used in simulations for training veterinarians and can be used for tasks such as lifting animals. Until robot-assisted surgical equipment becomes far less expensive and proves to add value to current laparoscopic procedures it seems unlikely to become incorporated into veterinary practice. However, robot assistants, robotic prostheses, hospital disinfectant machines, and microrobots that conduct endoscopic examinations or treat patients are distinct possibilities for the veterinary practice of the future. Indeed, it may not be long before there are robotics veterinarians who provide care for animals with prosthetic limbs or implanted chips or for robotic animals that are used in a variety of settings.

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Carlton Gyles

(Opinions expressed in this column are those of the Editor)

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artificielle afin d'aider la prise de décisions (1). En neurochirurgie, Modus V, un bras robotique automatisé et un microscope numérique, est construit par une compagnie de Toronto et se fonde sur la technologie du Canadarm de la navette spatiale (3). Le bras suit les instruments chirurgicaux, bouge automatiquement jusqu'à l'endroit approprié où le chirurgien travaille et projette une image à haute résolution magnifiée sur un écran.

Les prothèses bénéficient aussi considérablement de structures et de systèmes de contrôle nouveaux (2). Les membres robotiques avec une peau bionique et un système neural permettent un degré remarquable de contrôle par l'utilisateur. Les exosquelettes robotiques (orthoses) sont utilisés en réadaptation pour aider les personnes paralysées à marcher et à corriger des malformations (2). Les robots sont aussi utiles afin de garder les hôpitaux propres car les chambres sont désinfectées en utilisant une lumière ultraviolette à haute intensité appliquée par un robot (2).

L'endoscopie traditionnelle pourra bientôt être remplacée par de petits robots qui peuvent être conduits à des endroits particuliers pour effectuer diverses tâches, dont le prélèvement d'une biopsie ou la cautérisation d'un vaisseau qui saigne. Les microrobots peuvent être utilisés pour voyager dans les vaisseaux sanguins et administrer un traitement comme de la radiation ou un médicament dans un endroit spécifique. Des capsules endoscopiques robotiques peuvent être avalées pour patrouiller le système digestif, recueillir des renseignements et envoyer des données diagnostiques à l'opérateur. Puis, il y a les infirmières robotiques conçues pour assister ou remplacer les infirmières surchargées en réalisant des tâches comme les entrées numériques, la surveillance des patients, les prélèvements sanguins et le déplacement des chariots. Un domaine vraiment excitant de la robotique médicale est le remplacement des antibiotiques. Le concept est que l'on peut utiliser des nanorobots dotés de récepteurs auxquels les bactéries peuvent s'attacher qui servent à attirer les bactéries dans le courant sanguin ou dans des foyers d'infection.

Est-ce que les progrès importants ont une place en médecine vétérinaire? Les robots sont actuellement utilisés dans des simulations pour former les médecins vétérinaires et ils peuvent être utilisés pour des tâches comme le soulèvement des animaux. Il semble improbable que l'équipement chirurgical assisté par robot soit intégré à la pratique vétérinaire avant que son prix ne devienne beaucoup plus abordable et qu'il ait été démontré qu'il ajoute de la valeur aux interventions laparoscopiques actuelles. Cependant, les assistants robots, les prothèses robotiques, les machines de désinfection des hôpitaux et les microrobots qui effectuent des examens endoscopiques représentent une possibilité réelle pour la médecine vétérinaire de l'avenir. En effet, il pourrait bientôt y avoir des vétérinaires robotiques qui fournissent des soins aux animaux qui ont des prothèses ou des puces implantées ou pour des animaux robotiques qui sont utilisés dans divers contextes.

Renvois

1. *Robot-Assisted Surgery.* Disponible au : https://aabme.asme.org/posts/robot-assisted-surgery Dernière consultation le 10 juin 2019.
2. *15 Medical Robots That Are Changing the World.* Disponible au : https://interestingengineering.com/15-medical-robots-that-are-changing-the-world Dernière consultation le 10 juin 2019.
3. *Modus V brings robotic assistance to neurosurgery.* Disponible au : https://searchhealthit.techtarget.com/feature/Modus-V-brings-robotic-assistance-to-neurosurgery Dernière consultation le 19 juin 2019. ■

Carlton Gyles

(Les opinions exprimées dans cette rubrique sont celles du rédacteur en chef.)

International Journal of Manufacturing, Materials, and Mechanical Engineering
Volume 7 • Issue 4 • October-December 2017

Robots in Medicine:
Past, Present and Future

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ABSTRACT

Robots are wide across used in several industrial applications. Robot applications are more found in medical industry in recent days. In initial days, robots were mostly used for simple surgeries and medical applications such as laparoscopic surgery and minimally invasive surgery in 1980's. At that time robotic surgeries were performed with the presence of surgeons in operation theatre. The present day technology has been so much advanced with more enhanced capabilities to perform several complicated tasks such as remote surgery and micro robotic surgery. The current paper discuss about the history and evolution of robots in medical industry and their latest technological advances, applications in various fields in medicine and limitations of robots in medical industry along with its future scope.

KEYWORDS

CASPAR, Cyber Knife, General Laparoscopy, Intra Corporal Systems, MINERVA, Minimally Invasive Surgery, Prosthetic, Radiology, RoboCouch, Synergistic, Transurethral Resection, Unicndylar Knee

1. INTRODUCTION

In present days, robots have occupied major stake in engineering applications. The first robot "UNIMATE" was introduced by George Devol in the year 1954. It is used in production and manufacturing (Camarillo et al., 2004). Robots were first introduced in medical industry in early 1980's. Based on the role of the robot, they can be classified as active, passive, synergistic, semi-active and intra corporal systems (Smith-Guerin et al.,2008). The active robots play significant role in medical industry than other classification due to their flexibility and adaptability.

Robots in medical industry are used for various applications such as diagnosis, support actions during the surgeries and to perform complicated surgeries (Susilo et al., 2009; Zhao et al., 2015; Gomes, 2011; Hockstein et al., 2007).

Robots have been introduced in orthopedics to help the patients to recover from physical disorders (Napper and Seaman, 1989; Xiong et al., 2009). Due to the reason that the medical tasks performed by robot are high accurate and thus leads to low human error.

The master slave robot configuration enables the surgery, even though the surgeon is far from the location of the patient (Schmidt et al., 2014; Bloss, 2012; Lee et al., 2015). The application of robots

DOI: 10.4018/IJMMME.2017100104

in treating surgery of tumor offers greater accuracy and flexibility (Bogue, 2011). This enables the doctors or radio specialists to minimize interaction with radioactive environment.

Even though the robots have reached to the greater heights, there exist certain limitations across each medical specialization. The next chapters discuss about classification of robots in medicine, history and evolution of medical robots, capabilities and their enhancement along with limitations.

2. CLASSIFICATION OF ROBOTS IN MEDICAL INDUSTRY

Robots used in medicine are classified into five types according to their actuation and applications (Smith-Guerin et al., 2008). Figure 1 shows tree of robot for each category represents the classification of robots and an example.

2.1. Passive Robots

These are the robots actuated by human operator (Smith-Guerin et al., 2008). The information about the position of the tool relative to the pre-planned data is displayed to the surgeon. The execution of the surgical action is completely performed by the surgeon (Mosges et al., 1989; Lavallee et al., 1994). Dynamic walking robot and AESOP endoscopic positioner are examples for passive robots (Smith-Guerin et al., 2008; Collins et al., 2001).

Automated Endoscopic System for Optimal Positioning (AESOP) represented in Figure 2 is a voice controlled robot which is used to position an endoscope (Stoianovici, 2000). It was developed by Defense Advanced Research Projects Agency (DARPA), Computer Motion Inc. in 1989 and received FDA clearance in 1994 (Hockstein et al., 2007; Unger et al., 1994). It consists of motorized joints where the surgeon controls it with foot and hand (Kavoussi et al., 1994). It also consists of Hermes Voice-activation to control it with few simple voice commands (Ballantyne, 2002). It does not perform any invasive manipulation rather it is used only for endoscopy purpose (Camarillo et al., 2004).

2.2. Active Robots

These types of robots are completely actuated where interaction between the robot and the surgeon is very minimal (Smith-Guerin et al., 2008). The main purpose of the robot is to hold a sensor or a surgical tool or to machine the bone without any involvement of the human operator (Paul et al., 1992). It can perform tasks without any human interaction. Laparoscopic camera holders, Telemanipulators, Da Vinci surgical system, Zeus surgical systems, ROBODOC, CASPAR, cyber knife are some of the examples of active robots.

CASPAR (Computer Assisted Surgical Planning and Robotic system) is used for complete knee and hip replacement, the technology followed in this is very much advanced, which reduces the role of the surgeon, with the help of CASPAR the surgeon performs the operation through 3D visualization

Figure 1. Classification of robots in medicine

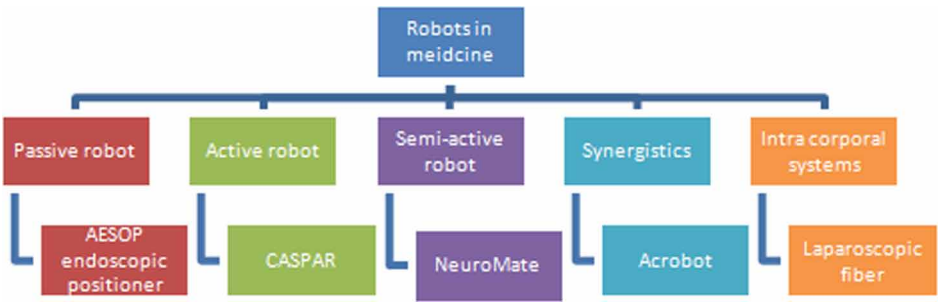


Figure 2. AESOP endoscopic positioner (Source: Computer Motion Inc.)

on screen. It performs operations with precision of tenth of millimeters (Gomes, 2011). A CASPAR robot is shown in Figure 3.

2.3. Semi Active Robots

In these robots, only some of the joints are actuated. These robots need involvement of both the surgeon and the robot for complete realization of the tasks (Smith-Guerin et al., 2008). It consists of a dedicated hardware to constrain the surgeon actions. It aligns a linear drilling trajectory through which the surgeon executes the task. So, it is called as the mechanical guide which is kept in position (Lavallee et al., 1992; Radermacher et al., 1994). The robot is used for pre-positioning and surgical action is done by the surgeon. Neuromate for brain biopsy is an example for semi-active robots.

NeuroMate is used in stereotactic neurosurgery presented in Figure 4. Its main function is to define the perfect trajectory for the drill and probe by using pre-operative images. It acts as a mechanical guide by positioning the tool at correct spot for insertion and to lock its joint (Camarillo et al., 2004; Cleary and Nguyen, 2001). In this, both the surgeon and the robot perform the operation (Beasley, 2012).

2.4. Synergistic Robots

Synergistic robots are semi-active robots which are guided by only for human gestures (Smith-Guerin et al., 2008). The unique difference with semi-active robots is programmable mechanical guidance. Acrobot for prosthetic knee implantation is best example for synergistic robot (Gomes, 2011).

Acrobot is also named as “active constraint robot” shown in Figure 5 (Camarillo et al., 2004). It is a bone drilling instrument which works on pre-operative images. Through this, the surgeon can directly feel the cutting forces and takes care of the undrilled parts (Davis, 2000; Jakopee et al., 2003). The surgeon controls the robot through “hands-on” mode. Here the stiffness of the robot automatically differs according to the tool tip position. The robot moves freely when the tool is in safe region and

Figure 3. CASPAR robot (Source: Maquet Surgical Site)

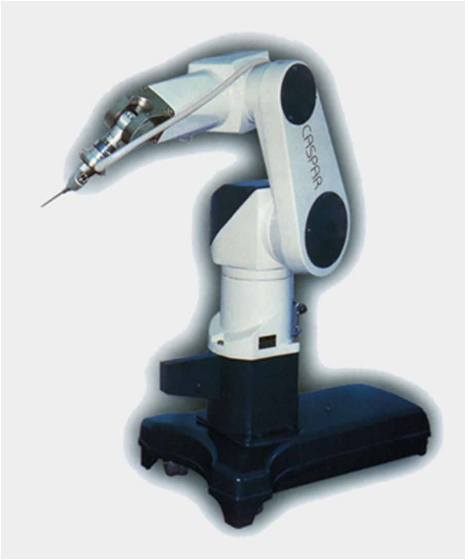
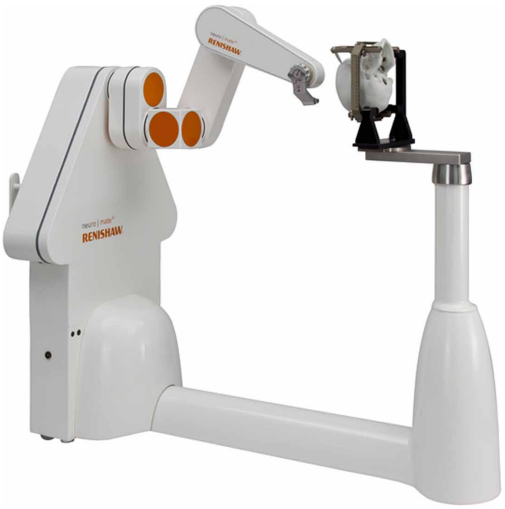


Figure 4. NeuroMate (Source: Renishaw)



its stiffness gradually increases when it reaches the boundary of the region. The previous version of this robot has some limitations such as the patient should be rigidly fixed and a gross positioning device is required to place the robot in position. The present version of this robot has overcome these limitations through remote center and mechanical tracking mechanism (Gomes, 2011).

2.5. Intra Corporal Systems

These are the small micro structures which are introduced into the body (Smith-Guerin et al., 2008). Laparoscopic fiber shown in Figure 6 is an example of intra corporal systems. The first solid state medical camera "Laparoscope" was introduced in 1982 for laparoscopic surgery. Laparoscope is

Figure 5. Acrobot sculpture (Source: Stanmore Sculpture)

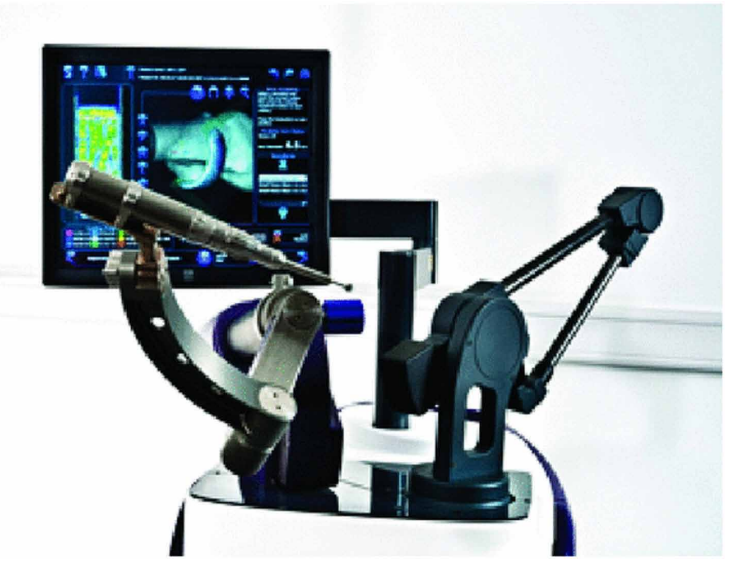


Figure 6. Laparoscopic fiber (Source: Alibaba.com)

a long fiber optic cable system used to view the affected area by coupling the cable from a long distance. Laparoscope is a telescopic rod lens system, connected to a video camera which can be of a single or triple chip design. Through this design, zoom and interchangeable fixed focus can be improved. In single chip design, sensors for red, green and blue light are presented in the camera which is embedded on a single Charge Coupled Device (CCD). This CCD converts incoming light energy from visual scene into a digital signal. In triple chip design, a prism is present in the camera head unit which splits the incoming image into red, green and blue components. These components are directed into three separate CCD chips. The image developed in triple chip camera is of superior quality which gives good color definition and clarity but is more expensive and heavier.

3. HISTORY AND EVOLUTION OF ROBOTS IN MEDICAL INDUSTRY

Robots in medicine were first introduced in early 1980's in the field of urology with laparoscopic surgery or Minimally Invasive Surgery (Camarillo et al., 2004). They have entered in the field of Orthopedics with hip replacement surgery in the year 1992 (Gomes, 2011). Robots for endoscopy were introduced with "AESOP endoscopic positioner" (Camarillo et al., 2004). Later two major surgical systems Zeus surgical system and Da Vinci surgical system were developed to perform complicated tasks. This Da Vinci surgical system becomes the first robot to receive Food and Drug Administration (FDA) clearance (Camarillo et al., 2004). Later Tele presence robots were found for remote surgery. In present days, many advances have been taken where micro robots play significant role in medical industry (Bogue, 2008). These micro robots move inside the body to deliver drugs, for imaging and to perform some complicated tasks. Table 1 informs about the historical evolution of robot usage in medical industry. A bar graph which is represented in Figure 7 gives the information about the yearly evolution of robots in medical industry.

4. APPLICATIONS OF ROBOTS IN MEDICAL INDUSTRY

It is observed, robots were most used for neuro surgery applications and orthopedics due to the need of high precision and accuracy, next to these, robots were found in radiotherapy with higher stake to reduce the radioactive environment interaction. A pie chart depicting the robot occupation in medical industry is shown in Figure 8.

5. CAPABILITIES AND ENHANCEMENT OF ROBOTS IN MEDICAL INDUSTRY

5.1. Neurology

Brain surgery is the complicated task out of all. It includes operating a covered target surrounded by sensitive tissues. This task is performed in view of medical pictures.

The first used robot "PUMA-560" in human surgery for brain biopsy was performed in 1985 utilizing a Computed Tomography (CT) picture and a stereotactic frame (Kwoh, 1988). This robot defines a direction for a biopsy by keeping the probe orientation towards the biopsy which is manipulated by the surgeon. This orientation was defined by using a preoperative CT on a stereotactic frame joined to a patient's skull. This robot was suspended after the robot organization was purchased out because of few security concerns (Beasley, 2012).

In 1991, MINERVA robot (University of Lausanne, Switzerland) was introduced for brain biopsy. It uses a real-time CT guidance to direct the tools into brain. This permits following targets even the brain tissue swells or moves because of operation. This was discontinued in 1993 because it can only perform single-dimensional incursions (Glauser et al., 1995).

The NeuroMate (by Renishaw) has a ConformiteEuropeenne (CE) mark and was granted Food and Drug Administration (FDA) clearance in 1997. This system is utilized for neuro-endoscopy, deep brain stimulation, radio surgery and transcranial magnetic stimulation (Varma and Eldridge, 2006).

Another robot called Path finder (Prosurgeries, formerly Armstrong Health care LTD.) shown in Figure 10 was cleared by FDA for neurosurgery in 2004 (Morgan et al., 2003). Through this system, surgeon determines a target and direction on a pre-operative medical image and robot directs the instrument into position with sub millimeter accuracy (Deacon et al., 2010). It is also used for controlling needles for biopsy and managing drills to make burr holes (Brodie and Eljamel, 2011).

Renaissance (Mazor robotics, the original frame work was named as spine assist) shown in Figure 9 was approved by FDA in 2011 and received CE mark for spinal and brain surgeries in 2011 (Joskowicz et al., 2011; Yang et al., 2010). This system comprises of a robot in the size of a soda-

Table.1. Historical evolution of robots in medical industry

S.NO	REFERENCE	YEAR	ROBOT	APPLICATION	DOMAIN
1	(Dogangil et al., 2010)	1983		Laparoscopic surgery	Urology
2	Internet source	1985	PUMA-560	Brain biopsy	Neurology
3	Internet source	1988	PROBOT	Prostate surgery	
4	(Hockstein et al., 2007; Unger et al., 1994)	1989	AESOP endoscopic positioner	Endoscopic surgery	
5	(Beasley, 2012)	1991	MINERVA	Brain biopsy	Neurology
6	(Schulz et al., 2007)	1992	ROBODOC	Hip replacement surgery	Orthopedics
7	Internet source	1993		Prosthetic knees	Rehabilitation
8	(Gomes, 2011)	1997	CASPAR	Knee and Hip surgery	Orthopedics
9	(Ballantyne, 2002)	1998	ZEUS surgical system	Endoscopic surgery	General Laparoscopy
10	Internet source	1999	ZEUS	Fallopian tubes operation	General Laparoscopy
11	Internet source	2000	Da Vinci surgical system	Laparoscopic surgery	General Laparoscopy
12	Internet source	2001	SOCRATES	Tele presence	
13	(Beasley, 2012)	2009	Free hand robot	Endoscopic holding	General Laparoscopy
14	(Stark et al., 2012)	2011	Telelap ALF-X	Laparoscopy	General Laparoscopy
15	(Low, 2011; Bogue, 2015)	2011	ReWalk Rehabilitation		Rehabilitation
16	Internet source	2013	IGAR	Breast cancer detection	
17	(Bogue, 2015; Bogue, 2009)	2014	INDIGO powered leg	Lower Body Exoskeleton	Rehabilitation
18	Internet source	2014		Leg rehabilitation	Orthopedics
19	Internet source	2014	LUKE SKYWALKER	Muscle contraction detection in prosthetics	Orthopedics
20	Internet source	2014	Three-armed robot	Surgery in womb	Gynecology
21	Internet source	2014	LITTLE MOE	Disinfection	
22	Internet source	2014	SCALLOP		
23	Internet source	2015	Magnetic rod	Spine surgery	
24	Internet source	2015	Nanometer drones	Drug delivery	
25	Internet source	2015	Robotic arm	Handling soft organs	
26	Internet source	2015	Rani robotic pill	Inject medication	
27	Internet source	2015	Origami robot	Remove cancer cells and unclog arteries	
28	Internet source	2015	Nano drone	Delivers drugs to heal	

Figure 7. Bar graph showing year on year development of robots in medicine

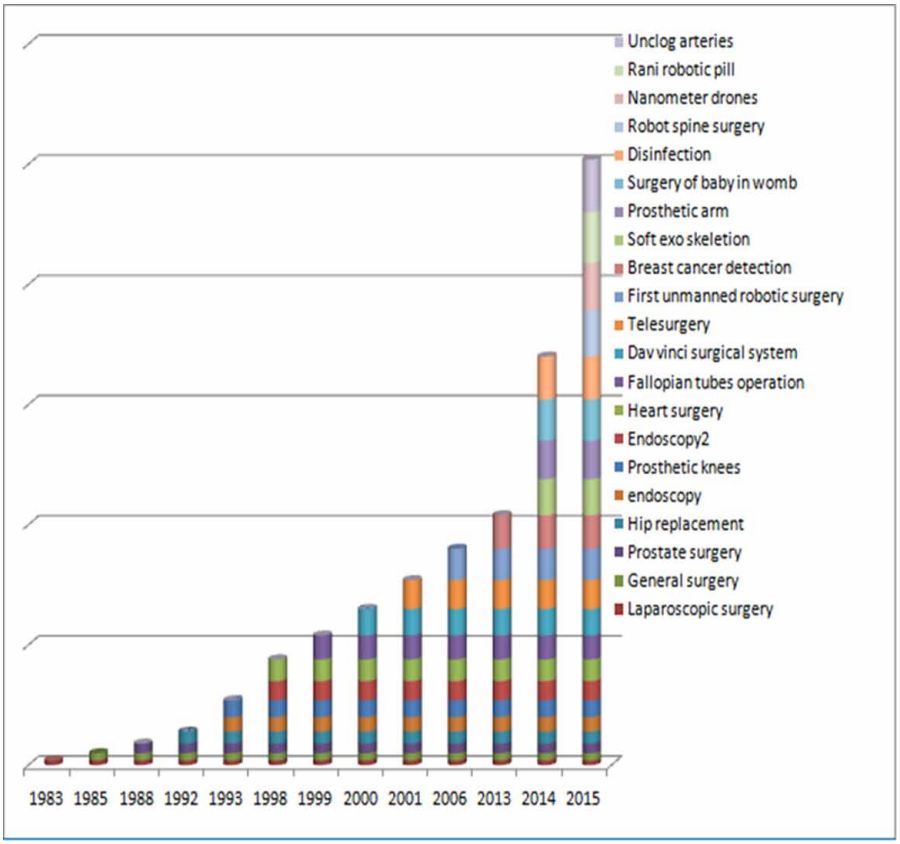
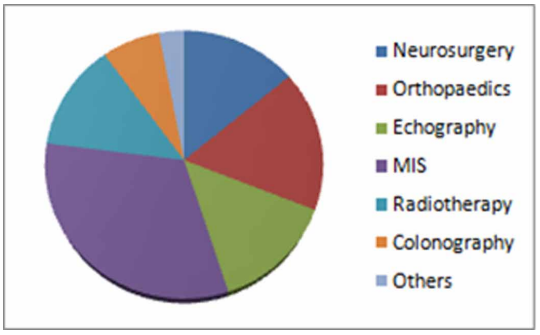


Figure 8. Pie chart showing percentage of robots used in different field in medicine



can which is directly mounted into the spine and gives tool direction based planning programming for Minimally Invasive Surgery (MIS), biopsies and electrode placement operations (Beasley, 2012)

5.2. Orthopedics

Robots are more advanced in the field of orthopedics. The expected advantage of robot help in orthopedics is precise and accurate bone resection (Beasley, 2012; Yang et al., 2010). Because of this, arrangement of implant with bone and increment in the contact area between the bone and implant can

Figure 9. Renaissance (Source: Mazor Robotics)

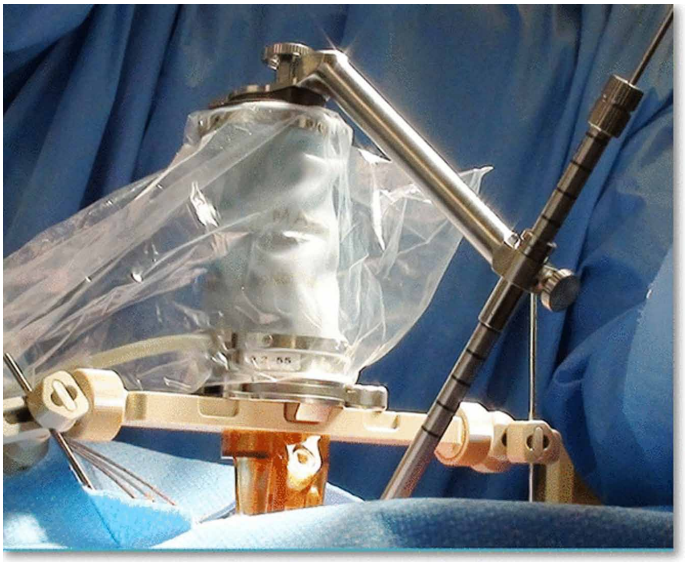


Figure 10. Path finder (Source: Prosurgeries)

be enhanced. This enhances the practical outcomes and implant life span (Davies, 2000). Orthopedic robots were so far used for hip and knee resurfacing or replacement except with the Renaissance which is used for spine assistance. In initial systems, the bones are fixed in place, which are localized using bone screws or pins.

In orthopedics, robots were first introduced in 1992 with Robodoc (Curexo Technology Corp, originally by Integrated Surgical Systems), which is used for hip replacement. It received a CE mark in 1996 and cleared FDA for hip replacement in 1998 and total knee replacement in 2009 presented in Figure 13 (Schulz et al., 2007). The robot is utilized as a part of conjunction with ORTHODOC, a

surgical planner, where the surgeon plans bone milling using preoperative CT. During this operation, the robot's pedestal is clamped with the patient's leg and a second clamp finds the femoral head to naturally end the robot if the leg moves. Then the milling operation is performed automatically by the ROBODOC using the surgical plan. Numerous early attempts included few autonomous movements in surgical robotics, which created few concerns about the safety of the patient and the doctor. Robodoc consists of force sensing on all axes and a six-axis force sensor at the wrist to address the safety concerns (Kazanzides et al., 1992). The force sensing is developed to permit the surgeon to physically move the robot arm, to change the speed of tool movement as a function of forces experienced in the bone milling and to check the safety of the patient and the doctor (Beasley, 2012).

CASPAR (Computer Assisted Surgical Planning and Robotics, Maquet surgical site) robotic system was introduced in 1997 for knee and hip surgery (Gomes, 2011). RIO robotic arm (MAKO surgical corp.) shown in Figure 11 was developed and received FDA clearance medical unicondylar knee components in 2008 (Pearle et al., 2010). In this both RIO and surgeon holds the tool and the surgeon moves in the surgical site. Through this the surgeon can move the tool easily because the robotic arm is developed to be low inertia and low friction (Rosen et al., 2011). The arm pushes back the surgeon's hand to oppose movements outside of the arranged cutting envelope. In this, the bone need not be fixed in place because it depends on the camera technology for tracking devices and bone sticks intra-operatively and quickly registering a pre-planned cutting envelope on the surgical site in the operating room. With this design, the system has guarantee that it can be used as a surgical training tool (Beasley, 2012).

The iBlock (Praxim Inc., previous generation the Praxiteles, FDA clearance 2010) was introduced for reducing the influence of robot on the cutting instrument shown in Figure 12(Plaskos et al., 2005). It prevents the relative motion between the bone and the robot by mounting it directly on the bone and adjusts a cutting plan to the surgeon to perform planar cuts manually through pre-operative plan. When compared to free hand navigation of cutting blocks, cutting accuracy is increased and surgical time is reduced (Koulalis et al., 2010).

For the unicondylar knee replacement, the Navio PFS (Blue Belt Technologies, CE mark 2012) utilizes a intra operative planning instead of depending on a CT scan (Brisson et al., 2004; Brisson,

Figure 11. RIO (Source: MAKO Surgical Corp.)

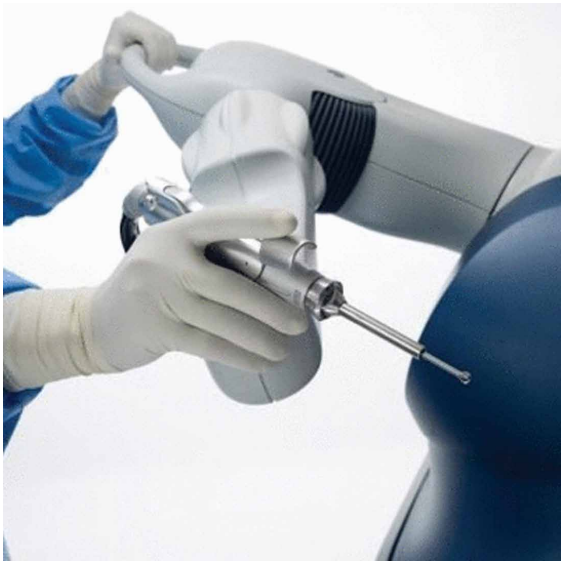


Figure 12. iBlock (Source: Praxim Inc.)

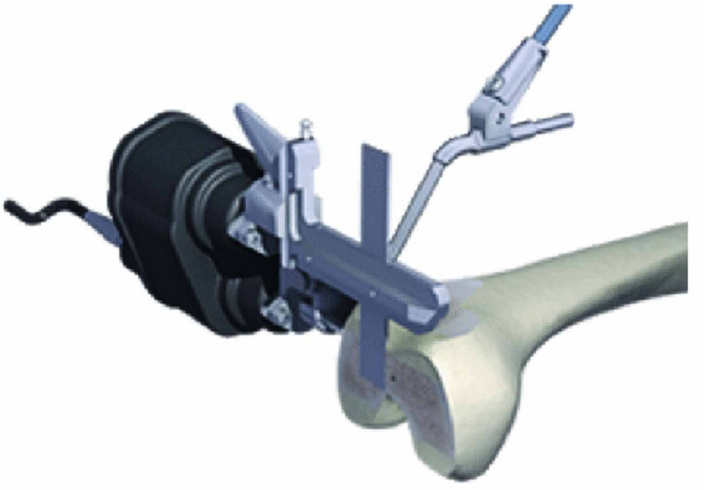
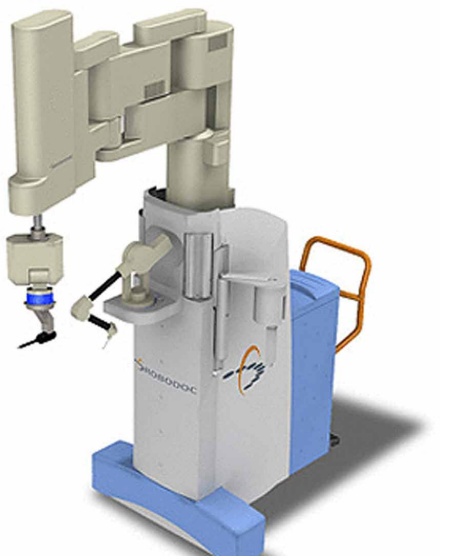


Figure 13. ROBODOC (Source: Curexo Technology Corp.)



2008). The drill instrument is followed during the operation and the drill bit is withdrawn when it should leave the planned cutting volume.

A synergistic robotic system "Stanmore Sculptor" with active constraints was designed to keep the surgeon in the arranged workspace (Yen and Davies, 2010). The Savile Row system also uses active constraints with the Stanmore Sculptor and joins a 3D model of the unicondylar knee implant into the surgical planning site to guarantee appropriate preparation of bone surface.

5.3. Radio Surgery

The operation of directing focused beams of ionizing radiation at the patient to treat tumors is called as radio surgery (Beasley, 2012; Leksell, 1983; Schulz and Agazaryan, 2011). A high-dosage radiation

Figure 14. Cyber knife (Source: Accuracy Inc.)

is delivered to the tumor by directing focused beams at various directions. Due to this, a significantly less radiation is received by the surrounding tissues. To treat the brain using stereotactic frames mounted to the skull, radio surgery was limited practically. Presently, the real-time tissue tracking can be attained with the aid of robots.

A frameless radio surgery system Cyber Knife (Accuracy Inc., FDA cleared 1999) shown in Figure 14 consists of a robotic arm which holds a linear accelerator, and a robotic patient table having six degree of freedom called the RoboCouch. To get real-time images in two orthogonal orientations simultaneously, it is provided with an X-ray imaging system (Alder et al., 1997; Gagnon et al., 2009). But a good definition of the tumor cannot be provided through the two simultaneous, intra operative X-ray images. But this is utilized to get a high-definition preoperative CT image. So a preplanned radiation dosage can be provided with a wide range of orientations by the robotic arm. The optional synchrony system is provided to track the targets that move during treatment (e.g., due to breathing). To continuously predict the target motion, it can optically track the surface of the tissue and correlate the movement of the tissue surface to the movement of radio-opaque fiducials that are inserted near the target (Hoogeman et al., 2009).

Another frameless system consisting of a linear accelerator called The Novalis with True Beam STx (Brain Lab Inc., FDA cleared 2000) was introduced for shaping the beam presented in Figure 15. For this purpose, it consists of micro-multi leaf collimators (Rock et al., 2004; Wurm et al., 2008). To optically track the skin mounted fiducials in real-time, an intra-operative X-rays compared with a CT is provided. A cone beam CT is present in the delivery system. Through the six degree of freedom robotic couch, the patient can be moved into the position. There is only major difference between Cyber knife and Novalis. In Cyber knife, radiation source has more degrees of freedom which are oriented around the patient. In case of the Novalis, the radiation beam can be shaped and thus the out-of-field dosage can be reduced (Liu et al., 2008; Abacioglu, 2012).

5.4. Exoskeleton and Prosthetics

Microprocessor-controlled prosthetics are introduced in 1993 with Intelligent Prosthetic knee (Chas. A. Blatchford & Sons, Ltd.) (Beasley, 2012).

Figure 15. Novalis with True Beam STx (Source: Brain Lab Inc.)

The C-leg knee prosthetic (OttoBock, FDA clearance and CE mark 1999) is developed to adjust the swing phase dynamics automatically. By controlling knee flexion, it improves the stability during the stance phase (Seymour et al., 2007).

The hand prosthetic "i-limb ultra-hand" (Touch Bionics, initially called as i-limb hand, FDA clearance and CE mark) was developed. It is the first commercial hand prosthetic consisting of five individually powered digits. It is controlled through myoelectric signals which are generated by the muscles in the remaining part of the patient's limb (Otr et al., 2010).

In 2011 ReWalk rehabilitation (Argo Medical Technologies, FDA clearance 2011) was designed for wheel chair users (Low, 2011; Bogue, 2015). It consists of metal brace which is used to support the legs and upper part of the body, electric motors to supply movement at the knees, ankles and hips, a backpack which consist of the computer and power supply and a tilt sensor. It controlled by a wireless remote control in which the commands stand, sit and walk are given to the ReWalk by the user. It requires crutches to walk and to get up from the chair. It is represented in Figure 16.

REX robotic exoskeleton (Rex bionics) has a pair of robotic legs linked with a strong hip girdle that enables a wheel chair user to stand up and walk. It does not need any crutches to provide stability. So, the user's hands are free to control by a keypad and a joystick. It is presented in Figure 17.

INDIGO powered leg (Orthosis prototype at OTWorld in Leipzig, Germany) was introduced in 2014. It is a lower body exoskeleton and battery powered which works up to 4 hours continuously. It consists of a gyroscope and inertial sensors that allow it to mirror natural human movement. To initiate standing or walking, the user leans forward and to stop and sit, he leans backward. It consists of vibratory feedback, LED indicators and a wireless software interface which provides control over parameters like stride length and step frequency (Bogue, 2015; Bogue, 2009).

5.5. General Laparoscopy

In 1980's, camera technology was developed for laparoscopic surgery. In this the operation is performed at the surgical site with small incisions by using tools and camera (Dogangil et al., 2010). Due to this patient's trauma, blood loss and length of hospital stay is reduced (Dogangil et al., 2010; Kuo and Dai, 2009).

Figure 16. ReWalk rehabilitation (Source: Agro Medical Technologies)

Figure 17. REX rehabilitation (Source: REX Bionics)

In 1988, the first robotic assistance for soft tissue surgery using an industrial robot is performed during the transurethral resection of prostate to remove soft tissue (Davies, 2000; Harris et al., 1997).

In 1998, Zeus robotic system for laparoscopic surgery was started which has computer motion's AESOP for endoscopy (Ballantyne, 2002). The tool arms of this system were Tele operated; the surgeon controls this with surgeon's console. It is a remote computer assisted Tele manipulator with interactive robotic arms. It can perform operation at a distance (Marescaux et al., 2001). Zeus is represented in Figure 19.

In 2000, another Tele operated system; Da Vinci surgical system shown in Figure 18(FDA cleared in 2000) was developed Internet source. In this the surgeon manipulates instrument controls with a console and the robot arms follow those motions. It consists of four arms, three for handling tools and one for holding camera (Camarillo et al., 2004; Olanrewaju et al., 2013). In this tools are more advanced than Zeus which has two degrees of freedom inside the patient. Its Endowrist reduces complexity of operation. It provides a video screen for each eye to display 3D video from 3D endoscope (Ballantyne, 2002). Initially it is cleared for radical prostatectomy and is now cleared by FDA for various procedures (Bodner et al., 2004; Tewari et al., 2003).

Figure 18. Da Vinci Surgical System (Source: Intuitive Surgical Inc)

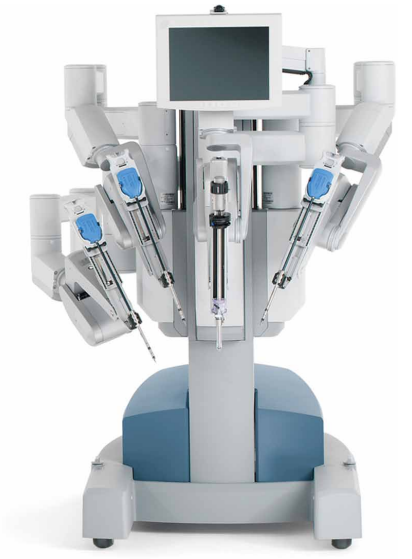
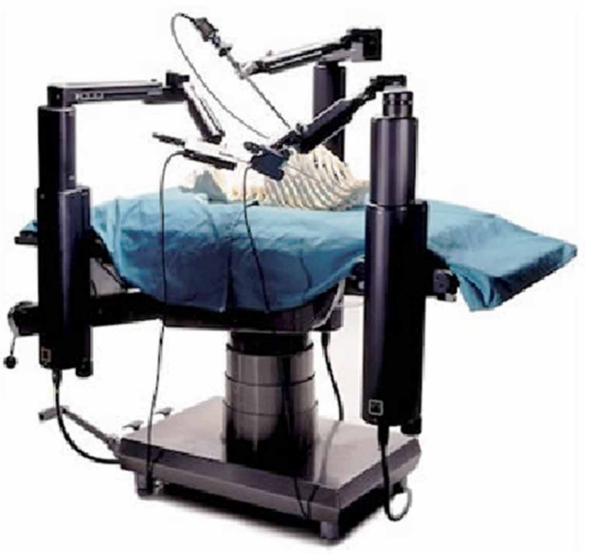


Figure 19. ZEUS Surgical System (Source: Medical Robotic Hub)



In 2009 Free hand robot (Free hand ltd; previously Free hand surgical, FDA clearance and CE mark in 2009) is an advanced endoscopic holder. This arm is more compact, easier to setup and cheaper (Beasley, 2012).

In 2011, Telelap ALF-X (SOFAR S.P.A, CE mark 2011) was developed for laparoscopy. It consists of four arms as Da Vinci surgical system. It has the ability to move the base of the manipulators away from the bed for about 80cm. It is advanced with realistic tactile sensing capability by measuring the tissue or tip forces from outside the patient (Stark et al., 2012).

A pie chart is shown in Figure 20 which represents the comparison of robots developed in different fields according to above analysis.

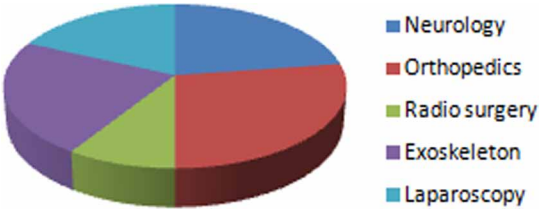
6. LIMITATIONS OF ROBOTS IN MEDICAL INDUSTRY

Few types of robotic surgeries take more time than normal human surgeries. For example, if the surgeon is not well experienced with the robot, then the robotic assisted heart surgery takes nearly twice the amount of time that a normal heart surgery takes. Investment and maintenance cost is high. It was estimated that if the cost of the robot is $1,500,000 then the procedure cost will be around $1500(for single procedure). More training is required i.e. surgeons should learn about traditional surgery as well as robotic surgery. This will become more critical for the surgeons. Robotic arms are large and bulky in size so that surgeons cannot perform operations efficiently. Tactile sensation for the surgeons is not provided. Due to the lack of touch sensation, surgeons couldn't predict the actual part to cut or removed (how much depth to be cut). Cell handling and DNA sequencing has become big challenge for the robots.

7. FUTURE SCOPE AND CONCLUSION

In present days, robots are rarely approved by FDA department and this has become a big challenge. So robots are developed according to the rules of FDA department. So its size is going to be decreased and performs operations with lesser risk. Since the size of the robot is large, surgeons couldn't perform their tasks perfectly. This also requires bulk spacing. So they are working on the robot, so that the size is going to be compact. They are going to provide touch sensation for the surgeons. If touch sensation is provided for the surgeons, they could perfectly predict the part to be cut. So, they could perform their tasks without any extra cut or incision in the body. Previously they used laparoscopic fiber for viewing internal parts of the body. For this purpose, Micro robots are going to be developed for viewing internal body parts. The predicted size of the micro robots is in micro meters. These are also used for internal repairing of body parts without the involvement of any tools or instruments. Through present robotic systems, cell handling and DNA repairing is not possible because of its tiny size. For this purpose, robots are developed with tiny size. Since the size of the robots is decreased,

Figure 20. Pie chart showing the comparison of robots developed in different fields according to previous mentioned analysis



they are working on them so that they can be used as antibodies. They are inserted into the body and whenever any bacteria or virus enters the body, it senses them and kills them. Shortly we can say that the responsibility of WBC's is taken care by the robots. Through present robotic systems either complete cut of the tumor is not taking place or extra number of cells is cut. New technologies are going to be developed in radio surgery so that complete cutting of tumors take place and no extra cells are removed.

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Does "AI" stand for augmenting inequality in the era of covid-19 healthcare?

Artificial intelligence can help tackle the covid-19 pandemic, but bias and discrimination in its design and deployment risk exacerbating existing health inequity argue **David Leslie and colleagues**

Among the most damaging characteristics of the covid-19 pandemic has been its disproportionate effect on disadvantaged communities. As the outbreak has spread globally, factors such as systemic racism, marginalisation, and structural inequality have created path dependencies that have led to poor health outcomes. These social determinants of infectious disease and vulnerability to disaster have converged to affect already disadvantaged communities with higher levels of economic instability, disease exposure, infection severity, and death. Artificial intelligence (AI) technologies—quantitative models that make statistical inferences from large datasets—are an important part of the health informatics toolkit used to fight contagious disease. AI is well known, however, to be susceptible to algorithmic biases that can entrench and augment existing inequality. Uncritically deploying AI in the fight against covid-19 thus risks amplifying the pandemic's adverse effects on vulnerable groups, exacerbating health inequity.

KEY MESSAGES

- The impact of covid-19 has fallen disproportionately on disadvantaged and vulnerable communities, and the use of artificial intelligence (AI) technologies to combat the pandemic risks compounding these inequities
- AI systems can introduce or reflect bias and discrimination in three ways: in patterns of health discrimination that become entrenched in datasets, in data representativeness, and in human choices made during the design, development, and deployment of these systems
- The use of AI threatens to exacerbate the disparate effect of covid-19 on marginalised, under-represented, and vulnerable groups, particularly black, Asian, and other minoritised ethnic people, older populations, and those of lower socioeconomic status
- To mitigate the compounding effects of AI on inequalities associated with covid-19, decision makers, technology developers, and health officials must account for the potential biases and inequities at all stages of the AI process

Cascading risks and harms

Interacting factors of health inequality include widespread disparities in living and working conditions; differential access to, and quality of, healthcare; systemic racism; and other deep-seated patterns of discrimination. These factors create disproportionate vulnerability to disease for disadvantaged communities, as a result of overcrowding, compelled work, "weathering" (that is, the condition of premature ageing and health deterioration due to continual stress), chronic disease, and compromised immune function.[1-3] This greater vulnerability manifests as increased risks for exposure to covid-19, susceptibility to infection, severity of infection, and death.[4-6] The evidence for these outcomes is rapidly increasing: mortality rates for covid-19 are more than double for those living in more deprived areas[7]; black, Asian, and minority ethnic Britons are up to twice as likely to die if they contract covid-19 in comparison with white Britons.[8 9] When controlling for age, black men and women are more than four times more likely to die than white men and women.[10]

Although AI systems hold promise for improved diagnostic and prognostic decision support, epidemiological monitoring and prediction, and vaccine discovery,[11 12]much research has reported that these systems can discriminate between, and create unequal outcomes in, different sociodemographic groups.[13] The combination of the disproportionate impact of covid-19 on vulnerable communities and the sociotechnical determinants of algorithmic bias and discrimination might deliver a brutal triple punch. Firstly, the use of biased AI models might be disproportionately harmfulto vulnerable groups who are not properly represented in training datasets, and who are already subject to widespread health inequality. Secondly, the use of safety critical AI tools for decision assistance in high stakes clinical environments might be more harmful to members of these groups owing to their life and death impacts on them. Lastly, discriminatory AI tools might compound the disproportionate damage inflicted on disadvantaged communities by the SARS-CoV-2 virus.

Despite their promise, AI systems are uniquely positioned to exacerbate health inequalities during the covid-19 pandemic if not responsibly designed and deployed. In this article, we show how the cascading effects of inequality and discrimination manifest in design and use of an AI system (fig 1). To mitigate these effects, we call for inclusive and responsible practices that ensure fair use of medical and public AI systems in times of crisis and normalcy alike.

Embedding inequality in AI systems

Patterns of health inequality permeate AI systems when bias and discrimination become entrenched in the conception, design, and use of these systems across three planes. Discriminatory structures become ingrained in the datasets used to train systems (eg, data from underserved communities are excluded owing to their lack of access to healthcare); deficiencies arise in data representativeness (eg, undersampling of vulnerable populations); and biases crop up across the development and implementation lifecycle (eg, failure to include clinically relevant demographic variables in the model leads to disparate performance for vulnerable subgroups).[14]

Health discrimination in datasets

AI technologies rely on large datasets. When biases from existing practices and institutional policies and norms affect those datasets, the algorithmic models they generate will reproduce inequities. In clinical and public health settings, biased judgment and decision making, as well as

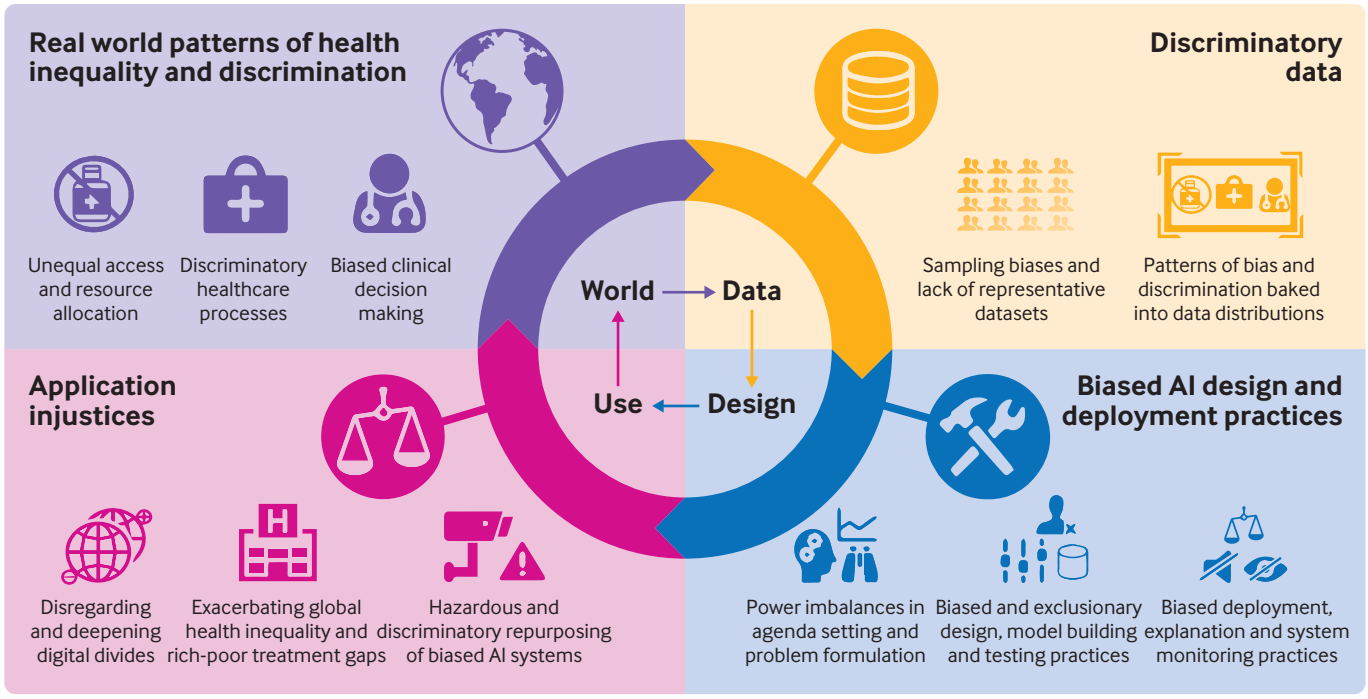

Fig 1 | Cascading effects of health inequality and discrimination manifest in the design and use of artificial intelligence (AI) systems

discriminatory healthcare processes, policies, and governance regimens can affect electronic health records, case notes, training curriculums, clinical trials, academic studies, and public health monitoring records. During clinical decision making, for example, well established biases against members of marginalised groups, such as African American[15 16] and LGBT[17 18] patients, can enter the clinical notes taken by healthcare workers during and after examination or treatment. If these free text notes are then used by natural language processing technologies to pick up symptom profiles or phenotypic characteristics, the real world biases that inform them will be silently tracked as well.

The datasets which are the basis of data driven AI and machine learning models thus reflect complex and historically situated practices, norms, and attitudes. This means that inferences drawn from such medical data by AI models to be used for diagnosis or prognosis might incorporate the biases of previous inequitable practices, and the use of models trained on these datasets could reinforce or amplify discriminatory structures. Risks of this kind of discrimination creep pose special challenges during the covid-19 pandemic. For instance, hospital systems are already using natural language processing technologies to extract diagnostic information from radiology and pathology reports and clinical notes.[19-21] As these capacities are shifted on to tasks for identifying clinically significant symptoms of SARS-CoV-2 infection,[22] hazards of embedding inequality will also increase. Where human biases are recorded in clinical notes, these discriminatory patterns will probably infiltrate the natural language processing supported AI models that draw on them. Similarly, if such models are also trained using unrepresentative or incomplete data from electronic health records that reflect disparities in healthcare access and quality, the resulting AI systems will probably reflect, repeat, and compound pre-existing structural discrimination.

Data representativeness

The datasets used to train, test, and validate AI models are too often insufficiently representative of the general public. For instance, datasets composed of electronic health records, genome databases, and biobanks often undersample those who have irregular or limited access to the healthcare system, such as minoritised ethnicities, immigrants, and socioeconomically disadvantaged groups.[23-25] The increased use of digital technologies, like smartphones, for health monitoring (eg, through symptom tracking apps) also creates potential for biased datasets. In the UK, more than 20% of the population aged 15 or older lack essential digital skills and up to 10% of some population subgroups do not own smartphones.[26] Datasets from pervasive sensing, mobile technologies, and social media can under-represent or exclude those without digital access. Whether originating from medical data research facilities or everyday technologies, biased datasets that are linked—such as in biomedical applications that combine pervasive sensing data with electronic health records[27]—will only exacerbate unrepresentativeness.

The prevalence and incidence of diseases and their risk factors often vary by population group. If datasets do not adequately cover populations at particular risk, trained prediction models that are used in clinical AI decision support might have lower sensitivity (true positive rates) for these populations and systematically underdetect the target condition.[28] Every time a prediction model which has been tailored to the members of a dominant group is applied in a "one-size-fits-all" manner to a disadvantaged group, the model might yield suboptimal results and be harmful for disadvantaged people.[29]

The data flows emerging from the covid-19 outbreak present a set of problems that could jeopardise attempts to attain balanced and representative datasets. Tendencies to produce health data silos create a channelling effect where usable electronic health records from patients who have contracted covid-19 overly reflect subpopulations who non-randomly have access to particular hospitals in certain, well-off neighbourhoods. This problem arises because resources needed

doi: 10.1136/bmj.n304 | *BMJ* 2021;372:n304 | thebmj

to ensure satisfactory dataset quality and integrity might be limited to digitally mature hospitals that disproportionately serve a privileged segment of a population to the exclusion of others. Where data from electronic health records resulting from these contexts contribute to the composition of AI training data, problems surrounding discriminatory effects arise. If such dataset imbalances are not dealt with, and if thorough analyses are not performed to determine the limitations of models trained on these data, they will probably not be sufficiently generalisable and transportable. The models will simply underfit members of vulnerable groups whose data were under-represented in the training set, and will perform less well for them.

Biases in the choices made for AI design and use

Lack of representativeness and patterns of discrimination are not the only sources of bias in AI systems. Legacies of institutional racism and the implicit—often unconscious—biases of AI developers and users might influence choices made in the design and deployment of AI, leading to the integration of discrimination and prejudice into both innovation processes and products.[30]

At the most basic level, the power to undertake health related AI innovation projects is vested with differential privileges and interests that might exacerbate existing health inequities. The sociodemographic composition (that is, class, race, sex, age) of those who set research and innovation agendas often does not reflect that of the communities most affected by the resulting projects.[31 32] This disparity lays the foundation for unequal outcomes from AI innovation. Decisions in setting the agenda include which clinical questions should be reformulated as statistical problems, and which kinds of data centric technologies should be developed. During the covid-19 pandemic this is of particular concern, as the urgency to find solutions and the institutional hierarchies in decision making are at cross purposes with consensus building mechanisms and with the diligence needed to ensure oversight and involvement of the community in setting the agenda.

Once an AI innovation project is under way, choices must be made about how to define target variables and their quantifiable proxies. At this stage of problem formulation, any latent biases of designers, developers, and researchers might allow structural health inequalities and injustices to be introduced in the model via label determinations (that is, choices made in the specification of target variables) that fail to capture underlying complexities of the social contexts of discrimination.[33] This bias was seen in a recent study, which showed that the label choice made by the producers of a commercial insurance risk prediction tool discriminated against millions of African Americans, whose level of chronic illness was systematically mismeasured because healthcare costs were used as a proxy for ill health.[34]

At the stages of extraction, collection, and wrangling of data, measurement errors and faulty data consolidation practices could lead to additional discrimination against disadvantaged communities. For example, if data on skin colour are not collected together with pulse oximetry data, it is almost impossible for AI models to correct for the effect of skin tone on oximetry readings.[35]

Similar discriminatory patterns can pass into design-time processes at the data preprocessing and model construction stages. The decisions made about inclusion of personal data such as age, ethnicity, sex, or socioeconomic status, will affect the way the model performs for vulnerable subgroups. When features such as ethnicity are integrated into models without careful consideration of potential confounders, those models risk identifying as biological, characteristics that have socioeconomic or environmental origins. As a result, structural racism might be integrated into the automated tools that support clinical practice. A well known example is the flawed "race correction" mechanism in commercial spirometer software.[36]

Lastly, AI systems might introduce unequal health outcomes during testing, implementation, and continuing use. For instance, in the implementation phase, clinicians who over-rely on AI decision support systems might take their recommendations at face value, even when these models might be faulty. On the other hand, clinicians who distrust AI decision support systems might discount their recommendations, even if they offer corrections to discrimination. For example, when a decision support model provides pulse oximetry values that have been correctly adjusted for skin tone, the results might conflict with a clinician's own preconceptions about the validity of raw oximetry data. These results might lead the clinician to dismiss the model's recommendation based upon their own potentially biased professional judgment.

Equity under pressure

During the covid-19 pandemic, demand for rapid response technological interventions might hinder responsible AI design and use.[37 38] In a living systematic review of over 100 covid-19 prediction models for diagnosis and prognosis, Wynants et al have found that owing to the pressure of rushed research, the proposed systems were at high risk of statistical bias, poorly reported, and overoptimistic. Up to this point, the authors have recommended that none of the models be used in medical practice.[39]

To make matters worse, some hospitals are hurriedly repurposing AI systems (which were developed for use, and trained on data, in situations other than the pandemic) for sensitive tasks like predicting the deterioration of infected patients who might need intensive care or mechanical ventilation.[40] These models run considerable risks of insufficient validation, inconsistent reliability, and poor generalisability due to unrepresentative samples and a mismatch between the population represented in the training data and those who are disparately affected by the outbreak.[41]

AI systems are similarly being swiftly repurposed in non-clinical domains, with tangible consequences for public health. In an attempt to curb the spread of covid-19, the United Sates prison system, for example, has used an algorithmic tool developed for measuring the risk of recidivism to determine which inmates will be released to home confinement. This tool has been shown to exhibit racial biases, and so repurposing it for the management of health risks makes black inmates more likely to remain confined and, consequently, subjected to increased exposure to covid-19 infection and disease related death.[42] At the beginning of the second US wave of the pandemic in June, such repurposing took place while the five largest known clusters of covid-19 in the US were at correctional institutions,[43] and against a backdrop of mass incarceration based on historic and systemic racism.[44]

Conclusion

AI could make a valuable contribution to clinical, research, and public health tools in the fight against covid-19. The widespread sense of urgency to innovate, however, should be tempered by the need

to consider existing health inequalities, disproportionate pandemic vulnerability, sociotechnical determinants of algorithmic discrimination, and the serious consequences of clinical and epidemiological AI applications. Without this consideration, patterns of systemic health inequity and bias will enter AI systems dedicated to tackling the pandemic, amplifying inequality, and subjecting disadvantaged communities to increasingly disproportionate harm.

With these dynamics in mind, it is essential to think not just of risks but also of remedies (fig 2). On the latter view, developing and deploying AI systems safely and responsibly in medicine and public health to combat covid-19 requires the following:

In technological development—Incorporation of diligent, deliberate, and end-to-end bias detection and mitigation protocols. Clinical expertise, inclusive community involvement, interdisciplinary knowledge, and ethical reflexivity must be embedded in AI project teams and innovation processes to help identify and remedy any discriminatory factors. Similarly, awareness of the social determinants of disparate vulnerability to covid-19 must be integrated into data gathering practices so that data on socioeconomic status can be combined with other race, ethnicity, and sensitive data to allow for scrutiny of subgroup differences in processing results.[45 46]

In medical and public health practices—Interpretation of the outputs of AI systems with careful consideration of potential algorithmic biases, and with understanding of the strengths and limitations of statistical reasoning and generalisation. Stakeholders in healthcare must use tools available in public health, epidemiology, evidence based medicine, and applied ethics to evaluate whether specific uses of the quantitative modelling of health data are appropriate, responsible, equitable, and safe.

In policy making—Benefits, limitations, and unintended consequences of AI systems must be considered carefully when setting innovation agendas, without discrimination. Policies will need to be formulated in processes that are open to all stakeholders and prioritise individual and community consent in determining the purpose and path of AI innovation projects.

Finally, as a society, we must deal effectively with systemic racism, wealth disparities, and other structural inequities, which are the root causes of discrimination and health inequalities and evident in algorithmic bias. If we do so, AI can help counter exacerbations of inequalities, instead of contributing to them.

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Competing interests: We have read and understood BMJ policy on declaration of interests and declare that we have no competing interests.

Provenance and peer review: Commissioned; externally peer reviewed.

This collection of articles was proposed by the WHO Department of Digital Health and Innovation and commissioned by *The BMJ*. *The BMJ* retained full editorial control over external peer review, editing, and publication of these articles. Open access fees were funded by WHO.

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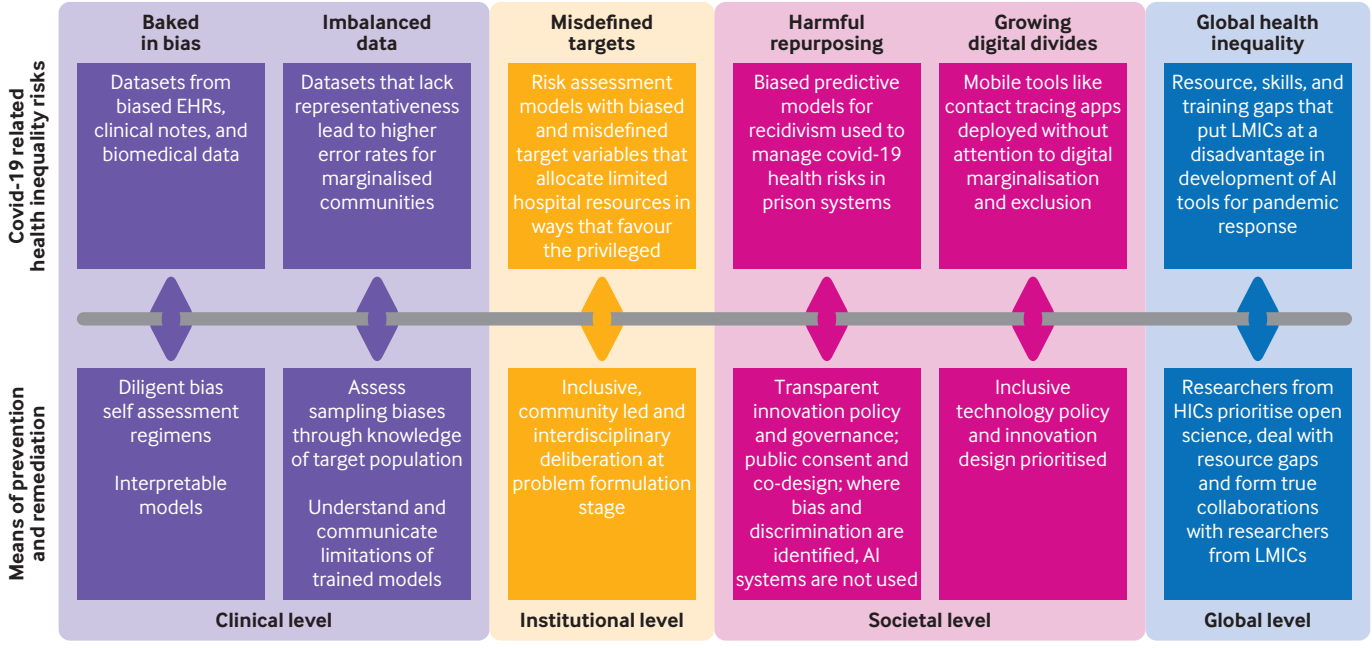

Fig 2 | Risks of, and remedies for, developing and deploying artificial intelligence (AI) systems safely. EHRs=electronic health records; HICs=high income countries; LMICs=low and middle income countries

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Cite this as: *BMJ* 2021;372:n304
http://dx.doi.org/10.1136/bmj.n304

radiation

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Review

Legal and Regulatory Framework for AI Solutions in Healthcare in EU, US, China, and Russia: New Scenarios after a Pandemic

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Simple Summary: We offer an overview of the state of regulation of AI in healthcare in the European Union, the United States of America, the China, and the Russian Federation and future strategies to make AI applications safe and useful.

Abstract: The COVID-19 crisis has exposed some of the most pressing challenges affecting healthcare and highlighted the benefits that robust integration of digital and AI technologies in the healthcare setting may bring. Although medical solutions based on AI are growing rapidly, regulatory issues and policy initiatives including ownership and control of data, data sharing, privacy protection, telemedicine, and accountability need to be carefully and continually addressed as AI research requires robust and ethical guidelines, demanding an update of the legal and regulatory framework all over the world. Several recently proposed regulatory frameworks provide a solid foundation but do not address a number of issues that may prevent algorithms from being fully trusted. A global effort is needed for an open, mature conversation about the best possible way to guard against and mitigate possible harms to realize the potential of AI across health systems in a respectful and ethical way. This conversation must include national and international policymakers, physicians, digital health and machine learning leaders from industry and academia. If this is done properly and in a timely fashion, the potential of AI in healthcare will be realized.

Keywords: artificial intelligence; policy; ethics; healthcare; regulation; accountability; telemedicine; data protection

Citation: Pesapane, F.; Bracchi, D.A.; Mulligan, J.F.; Linnikov, A.; Maslennikov, O.; Lanzavecchia, M.B.; Tantrige, P.; Stasolla, A.; Biondetti, P.; Giuggioli, P.F.; et al. Legal and Regulatory Framework for AI Solutions in Healthcare in EU, US, China, and Russia: New Scenarios after a Pandemic. *Radiation* **2021**, *1*, 261–276. https://doi.org/10.3390/radiation1040022

Academic Editor: Gabriele Multhoff

Received: 9 August 2021
Accepted: 11 October 2021
Published: 15 October 2021

1. Development in Healthcare Scenarios during and after COVID-19 Pandemic

The coronavirus disease (COVID-19) and its pressure on the healthcare system is happening at a time of technological optimism and promise. The digitalization of health data, together with the advent of artificial intelligence (AI) solutions, have the potential to

completely change the current pattern of the healthcare scenario and provide precise and predictive medical assessment for individuals in the future [1,2].

The new frontiers of research made possible by AI algorithms based on machine learning (ML) and deep learning (DL) give the technological possibility of using aggregated healthcare data to produce models that enable a true precision approach to medicine [3–8]. Such innovation may facilitate and improve the accuracy of diagnosis, tailoring treatments and targeting resources with maximum effectiveness in a timely and dynamic manner [7–11].

However, such innovative technology must be robust enough to avoid biased learning, which can happen when training datasets are too skewed, too small, and/or poorly annotated. This issue demands a global effort in the field of cross-disciplinary, international agreements for standardization, anonymization, validation, and data sharing. Moreover, it calls for continuous monitoring, starting from appropriate legal and regulatory policies to be shared among different countries and different health systems.

In the last two years, new technologies such as AI proved helpful in the management of the COVID-19 pandemic [12–18]. During the first months of 2020, chest computed-tomography scans showed the extent of lung damage caused by COVID-19; accordingly, efforts were established around the world to facilitate data sharing, model training, and scan assessment [10,15]. In Europe, 30 international partners created the Imaging COVID-19 AI, which provided an automated quantitative analysis of COVID-19 based on imaging [16].

Similarly, telemedicine has boomed. Many telemedicine platforms made their services available for free, including Doctolib in France, Kry in Sweden, and Adent Health in Denmark. Push Doctor, a company in the United Kingdom (U.K.) that has partnered with the National Health System (NHS), claimed in March that usage of their product had increased by 70% [19]. Moreover, NHS England recommended general practitioners to change face-to-face appointments to telephone or video appointments in March 2020 [20]. Regulation in telemedicine was also updated: the French government and German health insurance companies removed reimbursement restrictions on video consultations, and in the United States of America (U.S.), Medicare expanded its coverage to include telemedicine [19]. The British Medicine and Healthcare Products Regulatory Agency authorized fast-track approval of medical devices during the outbreak, and the Food and Drug Administration (FDA) in the U.S. stated that it did not intend to enforce requirements for certain lower risk device software functions, including symptom checkers [21]. Telemedicine advancements in the U.S. are discussed in a specific section below.

In many cases, such quick and wide response has already provided beneficial support, but at the same time, there have been some warning signs. Predictive models for COVID-19 are at high risk of bias, mostly due to nonrepresentative sample selection; when tested on a different, larger sample, their accuracy could decrease significantly [22]. Moreover, there have been concerns that some tools, particularly those used for location and contact tracing, may compromise personal privacy [1,23].

With different roles and competences, every healthcare stakeholder necessarily must evaluate and implement AI with a critical eye, keeping in mind current AI limitations—not only technical but even ethical limitations, such as the concern that AI algorithms may mirror human biases in decision making [1]. Since healthcare delivery may depend by ethnicity, some ethnic biases could inadvertently be built into healthcare algorithms. The intent behind the design of AI also needs to be considered, because some devices can be programmed to perform in unethical ways (i.e., to guide users toward clinical actions that would generate increased profits for their sellers by recommending specific tests or drugs) and not necessarily reflect better care [24]. The progress made in regard to AI and digital healthcare in a matter of months could have, under other circumstances, taken several years. Accordingly, it is even more important than ever to monitor advances carefully, to ensure that patients receive the best possible care, and to earn the trust of both the clinical community and patients. Avoiding missteps at this time is essential not just for the management of the pandemic, but to ensure the credibility and the future of digital AI-powered healthcare.

In this scenario, the issues showed in this paper acquire particular importance and urgency. They display the complexity of AI-based healthcare and highlight the need to develop policies and legal strategies that carefully consider the multiple dimensions of the integration process, and this need for multidisciplinary efforts to coordinate, validate and monitor the development and integration of AI tools in the healthcare [19]. Challenges such as organizational and technical barriers for health data use, the debate about the ownership of data and privacy protection, the regulation of data sharing and cybersecurity surrounding it, and accountability issues will have to be addressed as soon as possible.

This paper explores the status of legal and regulatory frameworks for healthcare AI in the European Union (EU), the U.S., China, and the Russian Federation, analyzing challenges, hurdles, and opportunities. The results are particularly significant, as the COVID-19 pandemic is triggering an unprecedented surge in the development of and demand for digital and AI technologies worldwide.

2. Organizational and Technical Barriers for the Adoption of AI in the Medical Field

Both ML and DL technologies require the availability of large amounts of comprehensive, verifiable datasets; integration into clinical workflows; and compliance with regulatory frameworks [1,23]. With improved global connectivity via the internet and cloud-based technologies, data access and distribution have become easier, with both beneficial and malicious outcomes [25]. Adequately regulated integration of health data and disease will provide unprecedented opportunities in the management of medical information at the interface of patients, physicians, hospitals, policymakers, and regulatory institutions. However, despite the pervasive enthusiasm about the potential of AI-based healthcare, there are only a few healthcare organizations with the data infrastructure required to collect the sensitive data needed to train AI algorithms for patients [26]. Consequently, published AI success stories fit the local population and/or the local practice patterns centered on these organizations and should not be expected to be directly applicable to other cohorts [27] (i.e., an AI algorithm trained on one specific population is not expected to have the same accuracy when applied elsewhere) [28].

3. Telehealth: A Boon Redefining Medicine for the 21st Century or a Short-Term Fix during the COVID-19 Pandemic?

Telehealth (or telemedicine as it is sometimes called) is literally "healing at a distance", with the provider in one location and the patient somewhere else [29]. Although the concept of telemedicine has existed for decades, developments in technology galvanized the ability to provide this service on a large-scale basis. In the U.S., historically, the largest hurdles to universal adoption of telehealth were twofold: first, insurance reimbursement was lacking; and second, the intricate and inconsistent web of state laws barred out-of-state doctors from practicing medicine across state lines.

With one fell swoop, the COVID-19 pandemic temporarily chipped away at these barriers. The U.S. Congress enacted legislation allowing the U.S. Department of Health and Human Services to issue waivers for telemedicine under Section 1135 of the Social Security Act. Additionally, former President D. Trump issued a Proclamation Declaring a National Emergency Concerning the Novel Coronavirus Disease Outbreak under the U.S. National Emergencies Act. The Emergency Proclamation authorizes HHS to offer additional waivers designed to increase providers' ability to treat the anticipated influx of ill patients.

The U.S. Centers for Medicare and Medicaid Services (CMS) now allows Medicare to cover telehealth visits and pay for such visits at the same rates as traditional, in-person visits. Private health insurance carriers quickly followed suit.

This waiver had a profound effect on the delivery of telehealth services in the U.S. University of California, San Diego Health (UCSDH), for example, had a long history of performing telemedicine on a limited basis before the pandemic. Its telemedicine infrastructure provided care to other remote centers for telestroke and telepsychiatry, amounting to up to 15 service lines in the past ten years. Through a small-scale pilot project, UCSDH provided 870 ambulatory home telemedicine video visits over the course

of three years. Because this foundation, though limited in scope, was in place, when the waivers for telemedicine were issued, UCSDH was able to leverage its experience to quickly provide wide telemedicine services during the pandemic. Over a 5-month period, UCSDH conducted over 119,500 ambulatory telemedicine evaluations (a remarkable increase from the pre-COVID-19 waiver period) [30].

The CMS also issued several nationwide blanket emergency waivers available throughout the duration of the pandemic, including a waiver of federal regulation 42 CFR 485.608(d), which required that critical access hospital staff (CAH) be certified in accordance with federal, state, and local laws and regulations. Under this waiver, out-of-state providers need no longer be in the same state as the patients to whom they provide telehealth services—if permitted by state law [31].

Each state has its own laws governing telemedicine, and the state in which the patient is located controls whether an out-of-state doctor must be licensed in that state at the time of the telehealth visit. While 40 states have issued waivers modifying their licensure requirements for telehealth visits by out-of-state physicians, the waivers are only effective during the pandemic [32].

Forty-nine state boards still require physicians engaging in telemedicine to be licensed in the state in which the patient is located [33]. One potential solution was advanced by the Interstate Medical Licensure Compact Commission (IMLCC). The IMLCC has an expedited pathway to licensure for qualified physicians seeking to obtain multiple licenses. Twenty-four states, Guam, and the District of Columbia enacted legislation to join the Compact. Still, with fewer than half of the states belonging to the Compact, there is still a long way to go for a permanent fix to this problem. While penalties vary from state to state, there are significant civil, professional, and even criminal licensure consequences for violating state telemedicine laws.

Several other challenges also remain with the delivery of telemedicine services in the U.S. Telemedicine is widening the existing gap in access to care. One recent study found that patients over 65 years old have the lowest odds of using telemedicine services, and that Black and Hispanic patients have lower odds of using these services than their White or Asian counterparts [34]. Additional concerns remain involving patient privacy. The HHS has waived penalties against providers that fail to comply with many of the U.S. HIPAA Privacy Rules until the Emergency Proclamation is rescinded, i.e., throughout the pandemic [35].

While we may be awed by technological advancements that allow for more medical services to be delivered remotely, long after the pandemic is over, Americans will continue to be challenged by the legal issues raised by telemedicine. The biggest impediment may be a real belief by state medical associations that telemedicine might adversely affect doctor incomes by allowing out-of-state providers to compete, resulting in continued rules restricting this highly efficient method of delivering medical services.

4. Regulatory Issues and Policy Initiatives

In the last few years, governments have started to promote data sharing [36]. For instance, anonymized benchmarking datasets with annotated diagnoses have been created to provide reference standards [37,38]. Existing examples of data-sharing efforts include biobanks and international consortia for medical imaging databases, such as the Cancer Imaging Archive (TCIA) [39], the Visual Concept Extraction Challenge in Radiology Project [40], the Cardiac Atlas Project [41], the U.K. Biobank [42], and the Kaggle Data Science Bowl [25], the latter of which represents a valuable step in the direction of an open-access database of anonymized medical images coupled with histology, clinical history, and genomic signatures.

Despite those hopeful examples, the amount of data sharing required for widespread adoption of AI technologies across different health systems demands still more efforts. It will probably depend more on the socioeconomic context of the health system in question rather than on technology itself, which has already been showed to be available and ready.

Once AI in healthcare is fully institutionalized and its rules are defined, it may be difficult to change those rules. To prevent this, state regulation and supervision should remain flexible and proactive [26].

The role of the government in the legal discipline of AI-based medical systems must manifest itself in the following activities:

- securing patients' medical privacy;
- creating regulatory sandboxes and experimental legal regimes;
- supervising medical organizations that use AI-based medical solutions;
- certifying software engineers for development of such systems;
- certifying AI-based medical systems and confirming their quality and effectiveness;
- avoiding uniformity in the process of AI-based medical systems development;
- providing state funding in the form of grants, subsidies, etc.

4.1. Legal and Regulatory Framework in EU

The "Medical Device Regulation" (MDR) should have been initially applied starting from 26 May 2020, but on 23 April 2020, the EU Council and the EU Parliament postponed the date of application for most of the MDR's provisions by one year, until 26 May 2021. On the other hand, the "In Vitro Diagnostic Medical Device Regulation" (IVDR) will apply, as initially provided, starting from 26 May 2022 [43].

The MDR and IVDR do not substantially impact the purposes of previous sets of EU laws. First, like the previous Directives [44,45], the new Regulations aim to:

- harmonize the single market by granting uniform standards for the quality and safety of medical devices;
- classify medical devices and in vitro diagnostics based on the relevant risk profiles by requiring different, specific assessment procedures in relation to such classifications;
- highlight responsibilities of notified bodies and competent authorities.

The main reasons behind the regulatory change consisted of divergent interpretations of the previous Directives [44,45], incidents concerning product performance, and lack of control of notified bodies. Thus, the legislation's revision was required to reach high standards of product quality and safety concerning evolving technologies, including AI, and to reconsolidate the EU's leading role in the medical-devices field [37]. The new Regulations should ensure a consistently high level of health protection and safety for EU citizens using AI-based products; the free and fair trade of the products throughout the EU; and the adaptation of EU legislation to the significant technological and scientific progress in the AI-based medical device sector over the last 20 years [43].

The scope of the new legislation includes a wider range of products, extends liability in relation to defective products, strengthens the requirements for clinical data and traceability of devices, increases clinical investigation requirements and manages risk to ensure patient safety, reinforces surveillance and management of medical devices as well as the lifecycle of in vitro diagnostic medical devices, and, finally, improves transparency relating to the use of personal data.

According to the new legislation, a software, whether as a component in a wider medical device or standing alone, is qualified as a medical device without any other specifics.

Starting from 24 May 2018, the General Data Protection Regulation (GDPR) applied in the EU. This new legislation is a suitable instrument to regulate AI because it has an extended territorial scope and wide rights for data subjects, providing, overall, more rights to citizens vis-à-vis information about the use of their personal data and giving clear responsibilities to people and entities using personal data [23,46,47].

The GDPR established rules to strengthen citizens' rights as regards the process of consent to the collection, use, and sharing of their personal data [23]. The regulation explained that consent must be explicit and unambiguous, and that data controllers must demonstrate that a person has given consent (in other words, the burden of the proof is with them). Consent must be informed, which it means it has to be demanded in intelligible

and easily accessible forms using clear and plain language. In addition, patients should be informed on how to withdraw consent prior to giving it.

Under the GDPR, patients have the right to access their own medical records and health data when they are being processed (i.e., with remote access). However, the GDPR does not make clear that access must be provided for free and even allows data controllers to charge a fee for administrative costs if data subjects ask for the data more than once [23].

4.2. Legal and Regulatory Framework in the U.S.

In the U.S., the 21st Century Cures Act [48] of 2016 defined the medical device as a tool "intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals" [49].

The FDA categorizes medical devices into three classes according to their use and risk (the higher the risk, the stricter the control) and regulates them accordingly.

The black box nature of AI applications will make it difficult for the FDA to approve all the new medical devices that are quickly being developed, given the volume of innovation and the complex nature of the testing and verification involved. For instance, the introduction of computer-assisted detection (CAD) software for mammography [49] required many years and extensive lobbying to obtain clearance from the FDA to be used as a second screening reader [50]. FDA clearance is even harder to obtain for an AI system that does not need humans' supervision and cannot be compared to predicated medical devices used as replacement for radiologists. Therefore, AI systems are usually presented today as merely support for physicians rather than as tools that substitute them [7,51–54].

The FDA and the International Medical Device Regulators Forum (IMDRF) recently assessed that AI technologies are different from traditional medical devices. The IMDRF is a voluntary group of medical device regulators including the EU, the U.S., Canada, Australia, Brazil, China, Japan, Russia, Singapore, and South Korea that works toward harmonizing international medical device regulation. The collaboration between IMDRF and the FDA defined a new category called "Software as Medical Device" (SaMD), pointing out for the need for an updated regulatory framework [25,54] that considers that AI systems must face safety challenges in the forms of complex environments, i.e., periods of learning (during which the system's behavior may be unpredictable) that may result in significant variation in the system's performance [54]. These organizations recommended a continuous iterative process based on real-world performance data and stated that low-risk SaMDs may not require independent review [25].

According to Thierer et al. [55], there are two main approaches to regulating new technologies. The "precautionary approach" gives some limits (or sometimes outright bans) to certain applications because of their potential risks: this means that these systems are never tested because of what could happen in the worst-case scenarios. On the contrary, the "permission-less innovation approach" allows experimentation to proceed freely; the issues that do arise are addressed as they emerge.

4.3. Legal and Regulatory Framework in China

Although COVID-19 has accelerated ongoing digital healthcare trends, in China, the regulation of AI is still developing [56].

China's regulatory body for life sciences products, the National Medical Product Administration (NMPA), certifies that products meet the requisite standards. However, once market approvals are granted, there is low control because of the continuous nature of software development and because software updates can so readily be pushed out to the public/market. For AI products that change second-to-second as the product adapts to a variety of inputs, the challenge is even more urgent.

Nevertheless, with a number of recent announcements and guidelines over the past few years, the NMPA has demonstrated a maturing approach [57].

The role of the NMPA Legal Agent, the key contact for the NMPA for each registered device, has correspondingly increased in importance. Like the EU and U.S., China requires a local entity before market clearance applications are accepted, but this need not be the manufacturer itself. A local distributor (that thereby tends to gain inordinate power over the foreign manufacturer) or a third-party service provider may also perform this role [56].

The NMPA has issued various guidelines relating to AI in catchup to the FDA, which approved an AI-based diabetes-related device in 2018. Furthermore, the NMPA issued in 2019 the "Technical Guideline on AI-Aided Software", in which it clarified that for AI software, version naming rules should cover algorithm-driven and data-driven software updates and should list all typical scenarios for major software updates [57].

For AI devices, the NMPA recognized that the risk-based method is the guiding principle in determining whether and when a product change needs to be filed.

Therefore, whether AI device updates require product change approval depends on statistical significance. Where the software maintains its effect based on the original application, there is no need to obtain preapproval.

In China, the following fast track pathways are available [56]:

- innovative approval;
- priority approval;
- emergency approval.

Innovative approval has a number of criteria to be satisfied, most relevantly that the product has significant clinical application value and a national patent and that no other similar products are already present on the market [56].

Priority review relates to treatment of rare diseases using devices with significant application value.

Emergency approvals are for public health crises, which was relevant in 2020 to face the COVID-19 pandemic, but such applications were no longer accepted in 2021.

4.4. Legal and Regulatory Framework in the Russian Federation

In the Russian Federation, the government has taken on the role of an observer and does not outrace developers with supervisory and regulatory measures. Striving instead to form an institutional basis for a wide range of AI development and application, Russia keeps up with the creation of different strategies, roadmaps, and standards. These documents have a defined, hierarchical structure. The National Program "Digital Economy of the Russian Federation" [58] consists of a description of the main directions, tasks, and goals for the development of the digital economy, and AI is mentioned in this document solely in the context of regulation and lawmaking.

The Decree of the President of the Russian Federation of 9 May 2017, 203, "On the Strategy for the Information Society Development in the Russian Federation for 2017–2030" [59] proclaimed the necessity and importance of intensification in the field of digital technologies, including AI. The Decree of the President of the Russian Federation of 10 October 2019, No. 490, "On the Development of Artificial Intelligence in the Russian Federation", together with the "National Strategy for the Artificial Intelligence Development" for the period up to 2030 [60], listed a number of AI solutions in healthcare, such as the creation of prediction models, reduction of risks and negative effects of pandemics, preventive screening, diagnostics based on medical images, automation, and increasing accuracy and effectiveness of physisicians.

In the Federal Law No 323-FZ of 21 November 2011, "On the Fundamentals of Healthcare in the Russian Federation", a "medical device" was defined as "any tools, equipment, devices, materials and other products used for medical purposes, necessary accessories and software" (article 38) [61]. Therefore, any AI solution, used independently or in combination with other medical devices, must be registered as a medical device, passing through clinical testing and acceptance according to article 36.1 of said Federal Law. The Russian supervisory authority—the Federal Service for Supervision of Healthcare

(Roszdravnadzor)—requires technical and clinical tests as well as examination of the safety, quality, and effectiveness of all medical devices prior to their use and sale.

Moreover, according to the Federal Law 152-FZ of 27 July 2006, "On Personal Data" [62], it is necessary to obtain consent even for anonymized data. Article 9 of this Federal Law dictated that "the subject of personal data decides on the provision of his personal data and agrees to their processing freely, of his own free will and in his interest". Consent to processing of personal data must be specific, informed, and conscientious. In accordance with Article 91 (part 2) of the Federal Law 323-FZ of 21 November 2011 [61], "On the Fundamentals of Healthcare in the Russian Federation", "processing of personal data in information systems in the healthcare sector is carried out in compliance with the requirements established by the legislation of the Russian Federation in the field of personal data and medical secrecy". Thus, for individuals and institutions dealing with personal data, there are legal risks and limitations that can be regarded as a factor that counteracts medical AI-software development.

Currently, in Russia, developers of medical software are required to register their software with Roszdravnadzor according to regulatory documents and standards, which are currently unavailable for AI-based solutions. However, the authorities are taking measures to remedy this situation. The first part of this standard was released in August 2020 and is available on the Federal Agency for Technical Regulation and Metrology (Rosstandart). State standard "Artificial Intelligence Systems in Clinical Medicine. Part 1. Clinical tests" will regulate the methodological basis of the clinical test process, the procedures for conducting clinical tests, accuracy indicators, and audits and quality control of medical AI systems. The other six parts are: "Technical test program and methodology"; "Application of quality management to retraining programs. Algorithm change protocol"; "Assessment and control of performance parameters"; "Requirements for the structure and application of a dataset for training and testing algorithms"; "General requirements for operation"; and "Life cycle processes".

According to the current regulation, it is exceedingly difficult to obtain subjects' consent to subsequent personal data processing. Therefore, it is difficult to use AI technologies for medical purposes, as they involve the analysis of information about thousands of patients and thus require many consents for the processing of personal data. In July 2020, it was proposed to remove the processing of personal data within the framework of experimental legal regimes from the norms of the federal laws "On Communications", "On Personal Data", and "On the Basics of Protecting Citizens' Health" [63]. However, while the usage of regulatory sandboxes and experimental regimes may represent a solution for understanding the problems, risks, and benefits of AI-based medical software, this proposal was regarded by many experts as very ambiguous and leading to many risks that would be hard to evaluate and prevent.

5. Ownership and Control of the Data

When using personal data such as the health information of patients, AI algorithms need to comply with regulatory frameworks. Accordingly, such data would need to be anonymized, or at least pseudo-anonymized, with an informed consent process that includes the possibility of wide distribution [64].

Therefore, the rules of patient privacy, the notions of patient confidentiality, and cybersecurity measures will be increasingly important in healthcare systems [65]. Currently, healthcare organizations are the owners (and, at the same time, the guardians) of patient data in the healthcare system. However, informed consent from patients would be mandatory should their data be used in a manner not pertaining to their direct care [23].

Some have argued that patients should be the own holder of their health data and subsequently consent to their data being used to develop AI solutions [66], but governance is needed to provide the appropriate regulations and surveillance. Both the GDPR in the EU and California's Consumer Privacy Act in the U.S. legitimately tried to regulate the

ownership of health data [23]. Although these regulations are necessary, they may limit the growth of smaller healthcare providers and technology organizations.

The GDPR requires informed consent before any collection of personal data, but it allows processing of anonymized health data without explicit patient consent in the interest of health care in the EU [23].

In the last decade, new issues arose complicating the health data ownership scenario. The healthcare system is in a slow transition from a hospital-centric to a more patient-centric data model [67]. This hinders the integration of new information acquired through health wearables, i.e., devices that consumers can wear to collect data about their personal health and exercise. Moreover, open data sharing has resulted in huge collections of data available in the cloud, which can be used by anyone to train and validate their algorithms [25,40] with the risk of disconnected and non-standardized cloud solutions [25,68].

With the GDPR, healthcare operators and regulatory bodies are called to closely protect patient data [23]. The development of huge health datasets including wide ranges of clinical/imaging data and pathologic information across multiple institutions for the development of AI algorithms will require a reexamination of issues surrounding patient privacy and informed consent. However, Article 23 of the GDPR allows member states to restrict data subject rights, as well as the principles outlined in Article 5, by way of a legislative measure that respects the essence of fundamental rights and freedoms. These restrictions, if they are embodied in necessary and proportionate measures, should aim to safeguard "important objectives of general public interest including monetary, budgetary and taxation matters, public health and social security". With the COVID-19 pandemic, processing personal data was necessary to take appropriate measures to contain the spread of the virus and mitigate its effects. In such a scenario, relevant personal data can be processed in accordance with both Articles 6(1)(d) and (e) of the GDPR because they are necessary either to protect the vital interest of individuals or to safeguard the public interest or the exercise of official authority vested in the controller. Notably, Recital 46 of the GDPR explicitly mentions the monitoring of epidemics as a circumstance in which data processing may serve both important grounds of public interest and the vital interests of data subjects. Nevertheless, specific safeguards should be implemented because of the sensitivity of these categories of data. Among the possible safeguards, policymakers should take measures aimed at: (a) limiting access to the data, (b) establishing stricter retention times, (c) training staff, (d) minimizing the amount of processed data, and (e) keeping records of any related decision-making process.

The ownership of health data is also part of the discussion on the application of different ownership rules to original, deidentified, anonymized, and processed data [69]. Once again, only collaboration among patients, healthcare operators, and policymakers will be able to prevent the risks of inappropriate use of sensitive datasets, inaccurate or inappropriate disclosures, and limitations in deidentification techniques.

5.1. The Problem of Anonymization

In healthcare, a balance between privacy and better user experience is demanded. AI algorithms should use DL to provide patients' data without saving their personally identifiable information. Therefore, anonymization or at least deidentification (true anonymization is an irreversible process that is not easily achievable) must be performed to generate such dataset with removal of all personal health information [70].

However, current anonymization and deidentification techniques are still substandard [71]. There are no currently available certifications for tools or methods for anonymization because no known method can currently guarantee 100% data protection. If data is made anonymous, its information content is inevitably reduced and distorted.

In data anonymization, the conflict between security and usability means that so far, no European data protection authority has extensively evaluated or even certified technologies or methods for data anonymization outside of specific use cases [72]. Collaboration among

different institutions is crucial when sharing data to perform ML or DL studies that, by definition, are based on big data.

5.2. Data Protection and Cybersecurity Implications

The legal obligation to protect the privacy of data, especially health data, is a crucial priority, as the circulation of confidential information in huge numbers of copies among many unregulated companies is increasingly risky.

As access to vast amounts of medical data is needed to train AI algorithms [73], policies should prevent the collection of illicit or unverified sensitive data [74]. Although data privacy concerns are still growing, we still face a lack of unique and clear regulations in data protection and cybersecurity regulations [75].

The concept of physician–patient confidentiality requires that a doctor withholds medical information in line with the patient's wishes as long as this poses no risk to the patient or others [24]. Once a medical choice based on AI algorithms is integrated into clinical care, withholding information from digital data impairs the validity of algorithm-driven medical practice. The privacy of such health data must be protected against both external cyberattacks and the same bodies collecting it.

Per the EU Cybersecurity Directive [76], EU member states must respect some requirements to ensure that health operators take appropriate measures to minimize the impact of incidents and to preserve service continuity (Articles 14(2) and 16(2)) (Table 1). Moreover, according to Articles 14(3) and 16(3), supervisory authorities must be notified of incidents without undue delay [75,76].

Table 1. Regulatory framework in the EU on data protection.

Directive 95/46/EC	**Directive on Data Protection Was Replaced by the GDPR**
GDPR	Regulation on data protection Applied from 24 May 2018 Replaced Directive 95/46/EC
Directive (EU) 2016/1148	Directive on cybersecurity Applied from 10 May 2018

EC, European Community; GDPR, General Data Protection Regulation; EU, European Union.

In the U.S., the Health Insurance Portability and Accountability Act (HIPAA) is a compliance focus for health information [54], defining standards to protect patients' data and health information that apply to all healthcare providers, including insurers.

Cybersecurity is dealt with by the FDA, and providers must report only a limited number of risks their devices present and the actions taken to decrease vulnerability [54].

Considering that the amount of data and the number of AI applications can only grow, regulatory actions regarding cybersecurity will face continuous challenges [74]. Instead of resorting to government overregulation, a technological solution of cybersecurity implications is most necessary, as data protection can no longer rely on current technologies that allow the spreading of personal data at a large and uncontrolled scale [77]. Blockchain technology, an open-source software, may allow the creation of large, decentralized, and safe public databases, containing ordered records arranged in a block structure [78]. Different blocks are stored digitally, in nodes, using the computers of the blockchain network members themselves, and the information on all transactions are stored in the nodes [79]. Although blockchain technology is most famously used in field of economics (i.e., cryptocurrencies), its usefulness is extending to other fields, including health data [79]. Blockchain can be used to validate the provenance of and facilitate the distribution of data without compromising the quality of said data. As the blocks are impossible to change, it is impossible to delete or to modify anything without leaving a mark, and this is crucial in the case of sensitive data such as medical information. Unfortunately, the flipside of the coin is that

to obtain greater security, privacy is compromised. Patients would need to accept sharing their sensitive data without a central authority to decide what is right or wrong.

6. Accountability and Liability

Alongside AI regulations and data protection issues, there are other legal implications of AI and its use in healthcare, namely, accountability and liability.

Modern medicine is strongly shaped around a multidisciplinary approach. It involves not only medical professionals with different fields of expertise and levels of experience, but also professionals from radically different backgrounds, such as biomedical engineers and medical physicists. Multidisciplinary teamwork has greatly enhanced, both in quality and quantity, the level of healthcare provided to patients. That said, this approach also comes with its unique shortcomings, which include uncoordinated administrative support, insufficient circulation of relevant information, and an excessive focus on a professional's own specific point of view, to the detriment of a holistic, comprehensive evaluation of the patient's case.

Unavoidably, those shortcomings pose a significant challenge not only from a clinical perspective but from a juridical one, as they alter the ordinary criteria that regulate the assessment of medical liability, which—especially when it comes to criminal liability—are traditionally shaped with reference to the individual rather than to a team of a different professionals.

To address this challenge, legal systems have developed a number of consolidated principles aimed at assessing medical liability while taking into account both the different roles and levels/fields of expertise of each professional and the common duties that fall upon all the members of a medical team simply because they work toward the same goal (i.e., the well-being of the patient).

Those principles revolve around the so-called "principle of trust", first theorized by the German doctrine under the name "Vertrauensgrundsatz" [80], which is specifically designed to regulate (from a liability perspective) the various possible forms of collaboration among two or more human professionals. This brings us back to the core topic of this paper: what happens if one of the members of a medical team is an AI-based software or machine? To what extent can the principles that regulate the collaboration among human colleagues be applied when one of those colleagues is not human at all? Is there room—in the juridical mind as much as the clinical one—to conceive a "principle of trust" with reference to a form of intelligence that does not have a human nature? These questions might seem very abstract, but the answers that will be developed within each legal system will certainly lead to very tangible consequences, not only for hospitals and medical professionals but for the companies that produce and market clinical tools based on AI and for the agencies and public authorities that regulate the use of these tools.

For instance, in most European legal systems, the principles that govern the assessment of professional liability within a medical team provide that each member of the team, consistently with their own role and level/field of expertise, has a specific duty to challenge the decisions made by their colleagues anytime they have reasons to believe that those decisions could be detrimental to the patient's wellbeing, particularly if they are aware of any circumstance that would lead them to doubt their colleagues' reliability (among others, overtiredness, inexperience, or lack of information about a particular patient).

If we were to apply the same criteria to the hypothesis of collaboration between a human professional and an AI software, it would be crucial to establish the inherent value attributed to the opinion expressed by this kind of device, also considering that, in most cases, the human professional has no visibility of the reasoning behind such opinion, as AI devices can neither explain nor elaborate on the outcomes of their analysis.

As long as opinion expressed by the AI device aligns to the opinion of the human professional, there is no particular issue, as the AI device acts merely as a confirmation of a previously existing conviction (even though one could argue that the medical professional

might feel comforted in a wrong decision and be less inclined to seek consultation with their human colleagues).

On the other hand, if the opinion expressed by the AI device differs from the opinion of the medical professional, the situation becomes more complicated. Taking the situation to its extreme consequences, ultimately, the human professional needs to choose whether to trust the AI device over their own judgment, thereby taking advantage of the full potential of this technical innovation—even though they will be exposed to the liability arising from any mistake committed by the device—or to trust their own judgment over that of the AI device, thereby avoiding any potential liability for a mistake committed by the device.

This is not an easy choice, and not one that medical professionals should be left to face alone. It is crucial that both hospitals and professional associations take an active step toward their employees and members by offering specific instruments (such as guidelines, protocols, and training programs) that can help medical professionals to understand the functioning of the AI devices they use and, therefore, to better assess the reliability of the opinions offered by those same devices and resolve possible discrepancies.

Moreover, as soon as AI devices start making autonomous decisions about the management of patients, ceasing to be only a support tool, problems will arise as to whether their developers can be held accountable for their decisions. As a matter of fact, errors in AI happen mainly when confounding variables are correlated with pathologic entities in the training datasets rather than in actual symptoms. When AI devices make decisions, the decisions are based on a combination of the collected data and the algorithms the devices are based on (and what they learnt). Conclusions of AI algorithms may be unpredictable for humans [81] because, while we consider only the intuitive, AI can evaluate every potential scenario and detail, leaving humans with a decision not derived from a common basis [82,83]. Therefore, it is worth considering whether, when something fails following a decision made by an AI application, it might be the developer of that device, rather than the medical staff who relied on its opinion, that should be considered at fault.

Without some clear guidance and a proper understanding of the potential and limits of the increasingly advanced AI systems that are now being implemented in many hospitals, it can be very difficult for medical professionals to get to know those devices and, therefore, to build real confidence in the support they offer.

Furthermore, specific guidance issued by a reliable a source (be it a hospital or a professional association) could also represent a useful reference from a legal point of view, as abiding by such guidance may—to a certain extent—shield medical professionals from the criminal and civil liability potentially arising from malpractice claims/complaints. Of course, there will always be clinical cases wherein the complexity and peculiarity involved make it impossible to rely on existing guidelines. Nevertheless, guidelines and protocols represent the most common term of reference for courts and authorities that are required to assess the potential malpractice liability of medical professionals, even more so when the cases brought to their attention involve a significant degree of complexity (e.g., because of the number of professionals that handled the same case, or because of the involvement of an AI device).

Therefore, proper guidance could both help medical professionals exploit the full potential of AI devices and protect them against the setbacks of that same technology from a legal standpoint. This could greatly enhance the level of confidence with which both professionals and courts look at the introduction of AI devices in the medical field, as well as the level of trust that patients themselves put in this kind of nonhuman intelligence.

Medical liability cases—like medical practice itself—essentially revolve around the patient or the patient's family. Therefore, educating patients about the potential benefits of the use AI devices is just as important, from a legal perspective, as increasing the sensitivity of courts and authorities toward this very same subject.

In conclusion, although the complexity of AI makes unavoidable that some of its inner workings will always appear to be a black box [74], that is not enough to keep liability out of the question. Because, over the coming years, AI devices are bound to play an

increasingly crucial role in the healthcare scenario, the issue of accountability for AI-based decisions will need to be properly addressed by competent authorities, always keeping in mind the core ethical principles of the medical profession: to respect patients and to do good for them [24].

7. Conclusions

Some laws and policies about AI regulation in healthcare, such as the GDPR, have just entered into force. Although, in the short term, such policies may potentially delay AI implementation in healthcare, in the long term, they will facilitate implementation by promoting public trust and patient engagement. With an appropriate and updated legal and regulatory framework around healthcare all over world, good employment of AI may be helpful and powerful for both healthcare providers and patients. On the contrary, bad application of AI may be dangerous. Patients, physicians, and policymakers must work to find a balance that provides security, privacy protection, and ethical use of sensitive information to ensure both humane and regulated management of patients.

Although technological advancement will continue to create new situations for which policymakers will be demanded to create new laws and ethical standards, physicians and healthcare workers should never forget whom they should serve and therefore strictly adhere to their oath, "primum non nocere" (first, do no harm). For this reason, the ownership and control of data and the relevant accountability and responsibility need to be assessed and clarified to realize the potential of AI across health systems in a respectful and ethical way.

Author Contributions: Conceptualization, D.A.B. and G.C.; methodology, D.A.B.; investigation, F.P. and D.A.B.; data curation, D.A.B. and M.B.L.; writing—original draft preparation, F.P., D.A.B., J.F.M., A.L., O.M., M.B.L., P.T., A.S., P.B., P.F.G., E.C. and G.C.; writing—review and editing, F.P., M.B.L. and D.A.B., O.M., P.T.; supervision, G.C.; project administration, G.C. All authors have read and agreed to the published version of the manuscript.

Funding: This research received no external funding.

Conflicts of Interest: The authors declare no conflict of interest.

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Digital Health Laws and Regulations China 2022

ICLG - Digital Health Laws and Regulations - China Chapter covers digital health and healthcare IT, regulatory, digital health technologies, data use, data sharing, intellectual property, commercial agreements, AI and machine learning and liability.

Published: 24/02/2022

Chapter Content

Free Access

1. Digital Health

1.1 What is the general definition of "digital health" in your jurisdiction?

Digital health is not a legal term defined under the laws and regulations of the People's Republic of China ("PRC") but is frequently referred to in commercial contexts and industry policies.

Digital health usually refers to the development and use of digital technologies to popularise health knowledge and its implementation to related fields, covering the application of digital technologies such as the Internet of Things ("IoT"), artificial intelligence ("AI"), and big data in medical services and health management. Digital health usually utilises technologies such as big data and AI to provide solutions for medical treatment, clinical research, drug development, imaging diagnosis, health management and other medical and healthcare needs.

1.2 What are the key emerging digital health technologies in your jurisdiction?

The key emerging digital health technologies include AI, mHealth, wearable devices, robotics, 3D printing, blockchain, global positioning system ("GPS") technology and 5G technology.

1.3 What are the core legal issues in digital health for your jurisdiction?

Personal privacy protection and data security are the core legal issues in digital health. In addition, the monopoly of healthcare data, the liability for medical damage caused by medical AI, and the ethical risks brought by the application of AI diagnosis and treatment technology are also common legal issues in digital health.

1.4 What is the digital health market size for your jurisdiction?

Influenced by COVID-19, China's online medical advantages have been highlighted, and the market share of digital health has increased continuously. According to the digital health report "Analysis Report of China's Digital Health Industry in 2021 – Research on the Current Situation and Future Prospect of Industrial Scale", the number of online medical users had reached 215 million by December 2020, accounting for 21.7% of the total number of Internet users. The revenue of China's digital health market was CNY 218.1 billion in 2019, and is expected to increase to CNY 4,222.8 billion in 2030, with a compound annual growth rate of 30.9%.

1.5 What are the five largest (by revenue) digital health companies in your jurisdiction?

According to the List of Chinese Digital Health Enterprises released by the 2021 China International Digital Economy Exposition, the five largest digital health companies in China are Ping An HealthKonnect (intelligent medical insurance integration platform), JD Health (online pharmacy), We Doctor (Internet hospital), United Imaging (innovative medical devices) and MGI Tech (innovative medical devices).

2. Regulatory

2.1 What are the core healthcare regulatory schemes related to digital health in your jurisdiction?

The core healthcare regulatory schemes related to digital health include the following:

- Law of the PRC on the Promotion of Basic Medical and Health Care.
- Regulation on the Administration of Medical Institutions.
- Administrative Regulations on Application of Electronic Medical Records (for Trial Implementation).
- Administrative Measures on Standards, Security and Services of National Healthcare Big Data (for Trial Implementation).
- Administrative Measures for Internet-based Diagnosis (for Trial Implementation).
- Administrative Measures for Internet Hospitals (for Trial Implementation).
- Administrative Regulations on Telemedicine Services (for Trial Implementation) ("Administrative Regulations on Telemedicine Services").
- Guiding Opinions of the State Council on Vigorously Advancing the "Internet Plus" Action.
- Opinions of the General Office of the State Council on Promoting the Development of "Internet Plus Health Care".
- Notice of the National Health Commission's office on the Pilot Work of "Internet Plus Nursing Service".
- Guiding Opinions of the National Healthcare Security Administration on Improving the "Internet Plus" Medical Service Price and Medical Insurance Payment Policy.
- Guiding Opinions of the National Healthcare Security Administration on Actively Promoting the Medical Insurance Payment Work of "Internet Plus" Medical Services (Guiding Opinions of "Internet Plus" Medical Services).
- Information Security Technology-Guide for Health Data Security (GB/T 39725-2020).

2.2 What other core regulatory schemes (e.g., data privacy, anti-kickback, national security, etc.) apply to digital health in your jurisdiction?

The other core regulatory schemes include the following:

- Civil Code of the PRC ("Civil Code").
- Anti-Unfair Competition Law of the PRC ("Anti-Unfair Competition Law").
- Cybersecurity Law of the PRC ("Cybersecurity Law").
- Data Security Law of the PRC ("Data Security Law").
- Personal Information Protection Law of the PRC ("Personal Information Protection Law").
- Measures for Cybersecurity Review.
- Interim Provisions on Banning Commercial Bribery.
- Administrative Regulations on Human Genetic Resources of the PRC.
- Measures for the Administration of Population Health Information (for Trial Implementation).
- Measures for the Management of Scientific Data.
- Information Security Technology – Personal Information Security Specification (GB/T 35273-2020).

2.3 What regulatory schemes apply to consumer healthcare devices or software in particular?

The regulatory schemes which apply to consumer healthcare devices or software in particular, include the following:

- Law of the PRC on the Protection of Consumer Rights and Interests.
- Product Quality Law of the PRC ("Product Quality Law").
- E-Commerce Law of the PRC.
- Regulations on the Supervision and Administration of Medical Devices ("Medical Devices Regulations").
- Rules for the Classification of Medical Devices.
- Administrative Measures on the Registration and Recordation of Medical Devices.
- Measures for the Supervision and Administration of Medical Device Production.
- Measures for the Supervision and Administration of Business Operations of Medical Devices.
- Measures for the Supervision and Administration of Online Sale of Medical Devices.
- Guiding Principles for Technical Review of Medical Device Software Registration.
- Guiding Principles for Technical Review of Network Security Registration of Medical Devices.
- Guiding Principles for Technical Review of Mobile Medical Device Registration.
- Guiding Principles for Classification and Definition of Artificial Intelligence Medical Software Products ("Guiding Principles for AI Medical Software Products").
- Classification Catalogue of Medical Devices.

2.4 What are the principal regulatory authorities charged with enforcing the regulatory schemes? What is the scope of their respective jurisdictions?

The principal regulatory authorities include the following:

- The National Health Commission ("NHC"): The NHC primarily formulates and enforces national health policies and regulations pertaining to healthcare services, healthcare institutions and healthcare professionals. Internet-based diagnosis and treatment and remote consultations between healthcare institutions are both regulated by the NHC.
- The National Medical Products Administration("NMPA"): The NMPA regulates drugs, medical devices and cosmetics, and is responsible for the safety, supervision and management of standard formulation, registration, manufacturing and post-market risk management.
- National Healthcare Security Administration ("NHSA"): The NHSA is primarily responsible for formulating and implementing policies related to basic medical insurance ("BMI"), such as reimbursement, pricing and the procurement of drugs, medical consumables and healthcare services.
- Ministry of Industry and Information Technology ("MIIT"): The MIIT is responsible for the management of the Internet industry, the access management of the information and communication industry, and the construction of network and information security guarantee system in the information and communication field. In terms of digital health, MIIT is responsible for supervising relevant technology development, personal data protection, etc.
- Cyberspace Administration of China ("CAC"): The CAC is responsible for the overall planning and co-ordination of network security and relevant supervision and administration, including regulating the cross-border transfer of healthcare data, cybersecurity review of Internet hospitals, network personal privacy and information protection.
- State Administration for Market Regulation ("SAMR"): The SAMR is responsible for supervising the market order in market transactions, online commodity transactions and related services, and organising the investigation and punishment of illegal medical advertisements, Anti-Commercial-Bribery and other acts against unfair competition.
- The Ministry of Public Security ("MPS"): The MPS is responsible for enforcing the Cybersecurity Classified Protection System and investigating cybercrimes, including conducting inspections and recording filings for the related system completed by healthcare institutions (Internet hospitals are included), and investigating crimes related to infringement of personal data and illegal access to information systems.

2.5 What are the key areas of enforcement when it comes to digital health?

Personal information protection, data security and cybersecurity are the key areas of enforcement in relation to digital health. China has established the Personal Information Protection Law (effective since November 1, 2021), the Data Security Law and the Cybersecurity Law. The Multi-Level Protection Scheme ("MLPs") implemented in the field of cybersecurity, as a compulsory legal obligation stipulated by the Cybersecurity Law and relevant regulations, has become a main focus in enforcement in most industries, including digital health.

2.6 What regulations apply to Software as a Medical Device and its approval for clinical use?

The main applicable laws and regulations include: Medical Devices Regulations; Rules for the Classification of Medical Devices; Administrative Measures on the Registration and Recordation of Medical Devices; Measures for the Administration of the Clinical Use of Medical Devices; and Guiding Principles for AI Medical Software Products.

2.7 What regulations apply to Artificial Intelligence/Machine Learning powered digital health devices or software solutions and their approval for clinical use?

In addition to the relevant regulatory provisions applicable to medical devices, AI/Machine Learning ("ML") powered digital health devices or software solutions shall also comply with the Management Specification of AI Aided Diagnosis Technology and Management Specification of AI Aided Therapy Technology in terms of Special requirements for medical institutions to carry out AI-aided diagnosis technology and AI-aided treatment technology in relation to department setting, staffing, technical management, etc.

3. Digital Health Technologies

3.1 What are the core issues that apply to the following digital health technologies?

- **Telemedicine/Virtual Care**

Medical institutions shall comply with the Administrative Regulations on Telemedicine Services in terms of personnel setting, equipment and facilities, telemedicine service process, responsibility sharing and management.

- **Robotics**

The liability arising out of medical accidents caused by robots is difficult to identify, and the division of responsibilities among producers, operators and users of intelligent robots is more complex.

- **Wearables**

In accordance with Medical Devices Regulations and Rules for the Classification of Medical Devices, some wearables (such as hearing aids or pain relief therapeutic instruments) are regarded as medical devices, and are subject to the relevant regulatory requirements on medical devices.

- **Virtual Assistants (e.g. Alexa)**

For virtual assistants like Siri and Alexa, problems such as eavesdropping, leakage of personal privacy and information may occur.

- **Mobile Apps**

Mobile medical APPs involves patients' electronic medical records, health records, consultation information and image data, and is highly dependent on the network and information technology. When cybersecurity or technical security is attacked or threatened, privacy and information leakage may occur.

- **Software as a Medical Device**

In accordance with Medical Devices Regulations, Rules for the Classification of Medical Devices, and Guiding Principles for AI Medical Software Products, Software as a Medical Device ("SaMD") will be subject to the relevant regulatory requirements on medical devices.

- **Clinical Decision Support Software**

In accordance with Medical Devices Regulations, Rules for the Classification of Medical Devices, and Guiding Principles for AI Medical Software Products, it may be subject to the relevant regulatory requirements on medical devices.

- **AI/ML powered digital health solutions**

Please refer to question 2.7.

- **IoT and Connected Devices**

Most of the data stored or collected by the Internet of Things ("IoT") terminal belongs to sensitive medical information. Once important information is leaked or maliciously modified by hackers, it will lead to cybersecurity, data and information leakage problems.

- **3D Printing/Bioprinting**

The application of 3D bioprinting in medical treatment is still in the early stage of exploration, and no specific provisions for 3D bioprinting have been issued in China.

- **Digital Therapeutics**

At present, digital therapy products are generally supervised as a medical device, and are subject to relevant regulatory requirements on medical devices.

- **Natural Language Processing**

Natural language processing involves a large number of personal oral languages which are fed back to the natural language processing system for identification and processing and, therefore may lead to the problem of leakage of personal information and data.

3.2 What are the key issues for digital platform providers?

In terms of the healthcare sector, digital platform providers are highly regulated. In terms of industry access, digital platform providers need to apply for different business licences according to their business types, for example, where the business involves online data processing, voice and image communication and other business forms, the digital platform providers are required to obtain value-added telecom service qualification; where the digital platform providers provide users with drug and medical device information through the Internet, they shall obtain the qualification of an Internet drug information service. In addition, in the process of business operations, it is also necessary to comply with the above regulatory requirements on personal information protection, data security and cybersecurity.

4. Data Use

4.1 What are the key issues to consider for use of personal data?

Some of the key issues for the use of personal data include how to standardise the code of conduct in such different links as collection, storage, use, processing, transmission, provision, disclosure and deletion of personal information so as to ensure the rational use of personal information without infringement.

4.2 How do such considerations change depending on the nature of the entities involved?

In addition to meeting the general provisions on the use of personal data, entities of different natures shall also comply with other relevant provisions, e.g.:

- If the entity involved is a third party that obtains relevant personal information through sharing or joint processing in accordance with the terms of the relevant agreement, it shall process the personal information in accordance with the relevant agreement, and shall not process personal information beyond the agreed processing purpose and method. If it infringes on individuals' rights and interests in terms of personal information and causes damage, it shall bear joint and several liability in accordance with the law.

- If the entity involved is located overseas and has one of the following circumstances: 1) providing products or services to domestic natural persons; 2) analysing and evaluating the behaviour of domestic natural persons; and 3) under other circumstances stipulated by laws and administrative regulations, the said entity shall establish a special institution or designated representative within the territory of the PRC to handle matters related to personal information protection, and submit the name of the relevant institution or the name and contact information of the representative to the relevant department responsible for personal information protection.
- If the entity involved falls within the definition of the critical information infrastructure operator ("CIIO"), it shall also abide by the Regulations on Security Protection of Critical Information Infrastructure.

4.3 Which key regulatory requirements apply?

The Personal Information Protection Law and other relevant laws and regulations stipulate the general rules on the collection and use of personal information. The use of personal information shall follow the principles of legality, legitimacy, necessity and integrity, and shall be open and transparent, and ensure the security and accuracy of personal information.

For example: 1) the data collection channel shall be legal, and advanced personal consent shall be obtained in accordance with the law. There must be an acknowledgment of the processing purpose, processing method, type of personal information processed, storage period, etc; 2) the processing of personal information shall have legal basis and shall not excessively collect personal information; and 3) personal information collectors shall formulate corresponding internal systems for information protection.

In addition, it should be noted that: 1) certain activities performed outside the PRC related to processing personal information of natural persons residing in the PRC will also be regulated by Chinese laws; and 2) when providing the personal information of those located outside of the PRC, one shall also comply with the following requirements: a) passing the security assessment organised by the national network information department; b) personal information protection certification by professional institutions; c) signing a contract with the overseas recipient according to the standard contract formulated by the national network information department to specify the rights and obligations of both parties; and d) special regulatory requirements of laws, administrative regulations or other conditions stipulated by the national network information department.

4.4 Do the regulations define the scope of data use?

According to the Personal Information Protection Law and other relevant provisions, the purpose, method and scope of processing personal information shall be clearly stated, and the processing shall be limited to the minimum scope to achieve the purpose of processing, and personal information shall not be excessively collected. The third party shall process personal information within the scope agreed by the individual on processing purpose, processing method and type of personal information.

In addition, the Information Security Technology – Personal Information Security Specification (GB/T35273-2020) provides detailed guidance on data use scenarios, assumptions and scope under various circumstances.

4.5 What are the key contractual considerations?

Where a contract is signed directly between an information processor with an information provider, the terms of the contract such as scope of data information processing, processing rules, exit restrictions, security measures, requirements for deletion, destruction or return of data and liability for breach of contract should be agreed on. The name and contact information of the personal information processor shall be informed in detail, and the purpose and method of processing the personal information, the type and retention period of the personal information processed, as well as other matters that are required to be informed according to laws and administrative regulations, shall be informed.

Where two or more personal information processors jointly process personal information, in addition to clearly specifying the above information, they shall also agree on their respective rights and obligations in the terms of the contracts.

4.6 What are the key legal issues in your jurisdiction with securing comprehensive rights to data that is used or collected?

The Civil Code clearly stipulates that a natural person's personal information shall be protected by law. For any unreasonable usage of personal information which infringes on the civil rights of individuals, the infringer shall bear civil liability according to law. For example, if a medical institution or its medical staff leak personal information, or disclose medical records without the consent of the patient, the medical institution shall bear tort liability.

The Criminal Law of the PRC stipulates corresponding criminal responsibility for infringement of citizens'

personal information and violation of relevant laws.

In addition, those who violate relevant laws and regulations such as the Cybersecurity Law of the PRC, the Data Security Law of the PRC, the Personal Information Protection Law of the PRC or the Anti-unfair Competition Law of the PRC will also face corresponding civil, administrative and even criminal liabilities.

5. Data Sharing

5.1 What are the key issues to consider when sharing personal data?

The key issues to consider when sharing personal data include the following:

- whether the sharing of personal data complies with the principles of necessity and realisation of legitimate purposes;

- whether to inform and obtain personal consent;
- whether it meets the requirements of security measures necessary for data sharing;
- whether the contract signed by all parties to data sharing include terms such as: the processing purpose; duration; processing method; type of personal information; protective measures; and the rights and obligations of both parties;
- whether there is personal data that is prohibited from being shared; and
- whether a cross-border data transfer is involved.

5.2 How do such considerations change depending on the nature of the entities involved?

In addition to meeting the general data sharing requirements, entities of different natures should also comply with other relevant provisions, for example: if the sharing party is the CIIO, it shall also abide by the Regulations on Security Protection of Critical Information Infrastructure.

However, if the receiving party is an overseas entity, specific conditions shall be met. For example, it has passed the security assessment organised by the national network information department, passed the personal information protection certification conducted by professional institutions, or entered into a contract with the overseas recipient according to the standard contract formulated by the national network information department to stipulate the rights and obligations of both parties.

5.3 Which key regulatory requirements apply when it comes to sharing data?

Firstly, the provider of sharing data shall: 1) conduct the impact assessment of personal information protection in advance; 2) inform the individual of the recipient's name, contact information, processing purpose, processing method and type of personal information, and obtain the individual's consent; 3) agree with the recipient on the purpose of entrusted processing, time limit, processing method, type and protection measures of personal information, as well as the rights and obligations of both parties; and 4) supervise the recipient's processing activities of personal information.

Secondly, the recipient of sharing data shall: 1) process personal information according to the agreement, and shall not process personal information beyond the agreed processing purpose and processing method; 2) if the relevant contract is not effective, invalid, revoked or terminated, the personal information shall be returned or deleted and shall not be retained; 3) without the consent of the provider, the recipient shall not entrust others to process personal information; 4) the recipient shall also take necessary measures to ensure the security of personal information and assist the provider in performing its personal information protection obligations.

In addition, attention should also be paid to the regulatory requirements involved in the cross-border transfer of personal information. For example, the CIIO or the personal information processor who processes personal information up to the amount specified by the national network information department shall store within China the personal information collected and generated in China. If it is really necessary to provide it to an overseas recipient, the security assessment organised by the national network information department shall be passed. (If the laws, administrative regulations and national network information department stipulate that the security assessment may not be carried out, such stipulations shall prevail.)

In accordance with the Measures for Cybersecurity Review (issued on December 28, 2021, and effective on February 15, 2022), if network platform operators who hold personal information of more than 1 million users are to be listed abroad, they shall apply to the cybersecurity review office for cybersecurity review.

6. Intellectual Property

6.1 What is the scope of patent protection?

Any technical solutions by using natural laws can be the subject matter of invention patents or utility model patents. The design patent is one of the patent types stipulated in the Patent Law of the PRC, and it protects new designs of the whole or part of the product in terms of shape, pattern and/or colour. After a patent is granted, unless otherwise stipulated in the Patent Law of the PRC, no entity or individual may exploit the patent without the permission of the patentee.

6.2 What is the scope of copyright protection?

The subject matter of copyright protection covers various works, which refers to intellectual achievements that are original and can be expressed in a certain form in the fields of literature, art and science. Computer software is one of the forms of works stipulated in the Copyright Law of the PRC. According to the Copyright Law of the PRC, copyright includes both property rights and personal rights, of which property rights mainly include: reproduction rights; distribution rights; and rental rights.

6.3 What is the scope of trade secret protection?

In accordance with Chinese laws, a trade secret refers to commercial information such as technical information and business operation information not known to the public, which is of commercial value, and for which the rights holder has adopted corresponding confidentiality measures. In accordance with the Anti-unfair Competition Law, obtaining trade secrets by improper means, disclosing and using trade secrets obtained by others by improper means, disclosing and using trade secrets in his possession but in violation of confidentiality obligations, or abetting, luring and helping others to commit such acts are all acts of infringing trade secrets and corresponding civil liabilities can be imposed. Serious trade secret infringements are defined as a criminal offence under the PRC Criminal Law and is punishable by up to 10 years of imprisonment.

6.4 What are the rules or laws that apply to academic technology transfers in your jurisdiction?

In China, the laws currently applicable to the academic technology transfers include the Law on Scientific and Technological Progress of the PRC (revised in 2021), the Law on Promoting Transfer and Commercialization of Scientific and Technological Achievements of the PRC (revised in 2015) and Several Provisions on the Implementation of the Law on Promoting Transfer and Commercialization of Scientific and Technological Achievements of the PRC issued by the State Council of the PRC in 2016. Such laws and regulations have adjusted previous policies in this field and clarified that the project undertakers, on the premise of no conflict with national security or national/public interests, are legitimately authorised to own relevant intellectual property rights arising from the government funded projects. Furthermore, the project undertakers are encouraged to legally transfer and commercialise these IP rights in various ways. However, any transfer or exclusive license to an overseas company shall be approved by the project administration organisation.

Public universities are conducting pilot programmes in guiding scientific researchers to transfer and commercialise IP rights in line with the laws. According to a document jointly issued by four national-level Ministries in 2020, Chinese universities will gradually establish disclosure systems for service inventions, establish and perfect technology transfer and IP management and operation departments, and explore the reforming of ownership of service inventions, such as division of ownership between universities and researchers, as well as permitting the scientific researchers to apply for patents in the form of non-service inventions in the event the university declines to apply for service patents.

6.5 What is the scope of intellectual property protection for Software as a Medical Device?

SaMD enjoys two forms of protection in China. Firstly, as it is regarded as a type of work protected under copyright, it does not require an application and examination process. Although the protection period is long, the disadvantage is that it is a form of expression which is capable of copyright protection and not a technical idea. Secondly, SaMD can be protected as it is considered an invention patent. It should be noted that pure algorithms or calculation rules are unpatentable subject matter under the Patent Law of the PRC: only when the technical features of the hardware are included in the claims can it be considered to be protected. Unlike copyright, what is protected by patent is the technical solution itself and, therefore this type of protection is thought to be more powerful.

6.6 Can an artificial intelligence device be named as an inventor of a patent in your jurisdiction?

In accordance with the current laws and regulations of the PRC, an inventor refers to a person who has made creative contributions to the substantive characteristics of an invention. It is generally understood that the inventor should be a natural person and, therefore, based on the current effective laws and regulations AI devices are unlikely to be recognised as inventors in China.

6.7 What are the core rules or laws related to government funded inventions in your jurisdiction?

Please refer to question 6.4.

7. Commercial Agreements

7.1 What considerations apply to collaborative improvements?

In the case of collaborative improvements, a written contract is required to agree on the rights and obligations of each party, and it is necessary to take into account how to handle the failure of collaborative improvements, as well as the ownership and use of rights of patents and non-patented technologies generated in the collaboration. In the absence of such a written contract, according to the provisions of the Civil Code, the right to apply for a patent shall be jointly owned by the parties to the collaborative improvements. If one party transfers the patent application right jointly owned with other parties, the other parties shall have the priority to such transfer under the same conditions. If there is no agreement or the agreement is not clear about the non-patented technological achievements, all parties have the right to use and transfer such achievements.

For Sino-foreign collaborative improvements, it is also necessary to consider the possible application of some mandatory laws and regulations. For example, if Chinese human genetic resources are involved, especially in cases exporting Chinese human genetic resource materials, according to the provisions of the Biosecurity Law of the PRC, an approval from the competent department shall be obtained. Furthermore, as for the technological achievements produced by using Chinese human genetic resources to carry out international cooperative research, the patent rights shall be jointly shared by the parties according to the Administrative Regulations on Human Genetic Resources of the PRC.

7.2 What considerations apply in agreements between healthcare and non-healthcare companies?

When signing agreements with non-healthcare companies, in addition to meeting the above requirements for data sharing, transmission and other processing, healthcare companies shall ensure that non-healthcare companies comply with the national and industrial regulations and requirements of the business they are engaged in, have the necessary business qualifications, have the abilities to implement relevant laws and regulations, implement relevant standards and guarantee data security, and have a comprehensive management system.

According to the Measures for Cybersecurity Review, if a healthcare company qualifies as a CIIO, when it purchases network products and services, it shall anticipate the potential national security risks after the products and services are put into use. Those products and services that affect or may affect national security shall be reported to the cybersecurity review office.

8. AI and Machine Learning

8.1 What is the role of machine learning in digital health?

As a common form of AI, machine learning is widely used in AI-aided diagnosis and treatment, medical imaging, wearable devices, genetic testing, pharmaceutical research, personal health management, and hospital management, etc.

8.2 How is training data licensed?

Data licensing in AI involves the licensing of relevant intellectual property rights, such as patents, software copyrights and trade secrets, and the licensed use shall apply to the Anti-Unfair Competition Law, the Patent Law of the PRC, the Regulations on the Protection of Computer Software and relevant provisions.

8.3 Who owns the intellectual property rights to algorithms that are improved by machine learning without active human involvement in the software development?

According to the existing effective laws and regulations, AI can neither be an author in the context of the Copyright Law, nor an inventor or designer in the context of the Patent Law. As a result, the existing laws and regulations do not cover this area. However, with the rapid development of AI technology, the legislation of intellectual property protection of AI-generated content is an important issue which needs to be urgently addressed. Chinese academia has been holding discussions on this issue as well. However, to date there is no unified understanding or relevant legislative proposals.

8.4 What commercial considerations apply to licensing data for use in machine learning?

Licensing data for use in machine learning in a business context mainly includes the applicable scope of licensing (duration, territory, sub-license or not), restrictions of data use, non-competition and confidentiality.

9. Liability

9.1 What theories of liability apply to adverse outcomes in digital health solutions?

The Civil Code, the Product Quality Law, Administrative Regulations on Telemedicine Services and relevant provisions have specified the liabilities of adverse outcomes in digital health solutions.

Where defects in medical devices and other digital health products cause personal injury or damage to others, victims may claim compensation from the manufacturer of the products or the vendor of the products. After one party makes compensation, that party has the right to seek indemnification from other parties who may be held liable.

If any damage or harm to a patient is caused during the course of diagnosis and treatment by the defects of digital health products, such patient may request compensations from the manufacturer or the relevant medical institution. After making the compensation, the relevant medical institution has the right to recover the losses from the liable medical device manufacturer.

When a dispute occurs in the course of remote medical services, the inviter shall bear corresponding legal liabilities for remote consultation, and the inviter and the invitee shall jointly bear corresponding legal liabilities for remote diagnosis. In terms of remote consultation, where medical institutions conduct remote consultation, the invitee shall provide diagnosis and treatment opinions, and the inviter shall specify the diagnosis and treatment plan. In terms of remote diagnosis, where an inviter and invitee establish a counterpart support or form a medical consortia and other cooperative relationships, the inviter shall carry out auxiliary examinations such as medical imaging, pathology, electrocardiograms, and ultrasound, the invited medical institution at a higher level shall conduct diagnosis, and the specific process shall be specified by the inviter and invitee

through an agreement.

9.2 What cross-border considerations are there?

According to the relevant provisions of the Personal Information Protection Law, where a personal information processor needs to provide personal information to any party outside China, it should first obtain the individual's consent and conduct advanced assessment of the impact on personal information protection. If the data involves medical and health data, advanced security assessment and review shall also be carried out.

Pursuant to the Special Administrative Measures (Negative List) for Foreign Investment Access (2021 version), the provision of medical services by foreign medical service providers in China is limited to the form of Sino-foreign joint ventures, and foreign medical service providers shall not establish medical institutions in China in the form of sole proprietorship. In addition, foreign investment in the development and application of human stem cells, genetic diagnosis and treatment technologies is prohibited in China.

Where imported digital medical devices are involved, registration or filing of medical devices shall be completed according to the Medical Devices Regulations and relevant provisions, and overseas applicants shall submit the application materials to the medical products regulatory authority through a domestic enterprise, as well as the documents certifying the approval of the marketing of such medical devices by the competent department in the country/region where the applicants are located. (It is not required to submit such documents for innovative medical devices that have not been marketed abroad.) Furthermore, the instructions and labels of imported medical devices shall meet the relevant requirements.

10. General

10.1 What are the key issues in Cloud-based services for digital health?

Cloud-based services mainly involve issues such as cybersecurity and data protection. Users upload data to the cloud and cloud service providers will manage the data. This may cause issues such as cybersecurity and data breaches and information leakage.

In addition, medical and health data are required to be stored within the territory of China, and those that need to be provided overseas shall be subject to a safety assessment and review according to the relevant regulations. As for service providers who have established data centres in multiple jurisdictions, there may be a risk of illegal cross-border data transfer.

10.2 What are the key issues that non-healthcare companies should consider before entering today's digital healthcare market?

Non-healthcare companies which plan to independently and directly engage in the digital health industry should first obtain the qualification licence for the corresponding business according to law. For example, those intending to provide online consultation, paid medical information and other services and construct a medical big data cloud-based platform through medical websites and APPs, shall obtain the approval of regulatory agencies and the relevant qualification licences.

If non-healthcare companies such as Internet companies intend to engage in the digital healthcare industry by cooperating with medical institutions, they shall agree with the cooperative medical institutions in a written agreement on the methods of cooperation, the responsibilities and rights of each party in medical services, information security, privacy protection and other aspects.

If non-healthcare companies choose to develop and produce AI medical software, wearable medical devices and other products, they shall also comply with relevant regulatory requirements on medical devices and AI-aided diagnosis technologies.

10.3 What are the key issues that venture capital and private equity firms should consider before investing in digital healthcare ventures?

Apart from business models, business prospects and other commercial factors, VC and PE investors should also pay attention to key issues such as market access requirements for the industry that the target company falls into, the business qualification and business license, core technologies and key technicians, procedures for obtaining ownership of relevant intellectual property rights, hardware facilities and cybersecurity protection, etc.

10.4 What are the key barrier(s) holding back widespread clinical adoption of digital health solutions in your jurisdiction?

Pursuant to the Measures for the Administration of the Clinical Application of Medical Technologies and relevant provisions, medical technologies in China are subject to a "categorised" regulation system. AI-aided diagnosis and AI-aided treatment fall within the scope of "restricted technology", and a medical institution intending to carry out the clinical application of such restricted technology shall conduct self-assessment according to the standards for the administration of the clinical application of medical technologies. A qualified institution may carry out clinical application and shall report to the health administrative department for filing. New medical technologies which have not been verified in clinical practice are considered to fall within the scope of "prohibitive technology" and cannot be used in clinical diagnosis and treatment.

The clinical adoption of digital health products which fall into the scope of medical devices shall go through approval or filing procedures according to the Administrative Measures on the Registration and Recordation of Medical Devices, the Measures for the Administration of the Clinical Use of Medical Devices and relevant provisions, and shall comply with the requirements in the aspects of clinical trial institutions, systems, procurement, operation management, and handling of safety involving the use of medical devices, failing which will result in administrative penalties from the competent authorities.

10.5 What are the key clinician certification bodies (e.g., American College of Radiology, etc.) in your jurisdiction that influence the clinical adoption of digital health solutions?

In China, there is no physician certification bodies that influence the clinical adoption of digital health solutions. The qualification licence and relevant requirements for physicians engaged in clinical adoption are mainly stipulated under the Physicians Law of the PRC, the Measures for the Administration of the Clinical Application of Medical Technologies, and the Measures for the Administration of the Clinical Use of Medical Devices and relevant provisions.

The China Medical Practitioner Association mainly performs the following duties: to implement industry management; formulate self-discipline rules; provide support such as legal assistance for medical practitioners; provide continuous education for medical practitioners; and organise academic meetings and seminars.

10.6 Are patients who utilise digital health solutions reimbursed by the government or private insurers in your jurisdiction? If so, does a digital health solution provider need to comply with any formal certification, registration or other requirements in order to be reimbursed?

In China, if patients have subscribed to or are covered by basic medical insurance, and the expenses of medical treatment items and medical service facilities are partially or completely covered by the basic medical insurance catalogue, the relevant expenses can be settled and reimbursed according to the medical service agreements signed between the government medical insurance agency and the designated medical insurance institutions. In addition, patients can purchase private insurance and be reimbursed for relevant medical expenses from private insurance companies.

After the promulgation of the Guiding Opinions of "Internet Plus" Medical Services on October 24, 2020, Internet Plus Medical Services was formally allowed under the medical insurance payment. The expenses of examination and prescription incurred from return visits in "Internet Plus Medical Services" designated medical insurance institutions by the insured in areas subject to overall planning can be reimbursed according to relevant regional medical insurance policies.

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The International Comparative Legal Guides and the International Business Reports are published by: Global Legal Group

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AI & SOCIETY (2021) 36:59–77
https://doi.org/10.1007/s00146-020-00992-2

ORIGINAL ARTICLE

The Chinese approach to artificial intelligence: an analysis of policy, ethics, and regulation

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Received: 21 September 2019 / Accepted: 17 May 2020 / Published online: 17 June 2020

Abstract
In July 2017, China's State Council released the country's strategy for developing artificial intelligence (AI), entitled 'New Generation Artificial Intelligence Development Plan' (新一代人工智能发展规划). This strategy outlined China's aims to become the world leader in AI by 2030, to monetise AI into a trillion-yuan (ca. 150 billion dollars) industry, and to emerge as the driving force in defining ethical norms and standards for AI. Several reports have analysed specific aspects of China's AI policies or have assessed the country's technical capabilities. Instead, in this article, we focus on the socio-political background and policy debates that are shaping China's AI strategy. In particular, we analyse the main strategic areas in which China is investing in AI and the concurrent ethical debates that are delimiting its use. By focusing on the policy backdrop, we seek to provide a more comprehensive and critical understanding of China's AI policy by bringing together debates and analyses of a wide array of policy documents.

Keywords Artificial intelligence · China · Cyber warfare · Digital ethics · Economic growth · Governance · Innovation · International competition · New Generation Artificial Intelligence Development Plan · Policy · Privacy · Social governance

1 Introduction

In March 2016, a Google DeepMind artificial intelligence (AI) designed for playing the board game Go (AlphaGo) defeated Lee Sedol, a South Korean professional Go player. At the time, Sedol had the second-highest number of Go international championship victories, yet lost against AlphaGo by four games to one (Boroweic 2016). While the match received some coverage in the West, it was a major event in China, where over 280 million people watched it live. Two government insiders described this match as a 'Sputnik moment' for the development of AI within China (Lee 2018, p. 3). Although there had been AI policy initiatives in the country previously, the victory for AlphaGo contributed to an increase in focus, as indicated by the 2017 'New Generation Artificial Intelligence Development Plan' (AIDP). The AIDP set out strategic aims and delineated the overarching goal of making China the world leader in AI by 2030.[1]

A limited number of reports have attempted to assess the plausibility of China's AI strategy given China's current technical capabilities (Ding 2018; "China AI Development Report" 2018). Others have sought to understand specific areas of development, for instance, security or economic growth (Barton et al. 2017; "Net Impact of AI on jobs in China" 2018; Allen 2019). However, to grasp the ramified implications and direction of the AIDP, it is insufficient to analyse specific elements in isolation or to consider only technical capabilities. Instead, a more comprehensive and critical analysis of the driving forces behind China's AI strategy, its political economy, cultural specificities, and the current relevant policy debates, is required to understand China's AI strategy. This is the task we undertake in this article.

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[1] In the rest of this article, we shall use 'China' or 'Chinese' to refer to the political, regulatory, and governance approach decided by the Chinese national government concerning the development and use of AI capabilities.

To provide this contextualised understanding, Sect. 2 maps relevant AI legislation in China. We argue that, although previous policy initiatives have stated an intent to develop AI, these efforts have been fractious and viewed AI as one of many tools in achieving a different set goal. In contrast, the AIDP is the first national-level legislative effort that focuses explicitly on the development of AI as a unified strategy. Following this, Sect. 3 analyses the interventions and impact of the AIDP on three strategic areas identified in the document, namely: international competition, economic growth, and social governance. Section 4 focuses on China's aim to develop ethical norms and standards for AI. There we argue that, although the debate is in its early stages, the desire to define normative boundaries for acceptable uses of AI is present and pressing. Altogether, this article seeks to provide a detailed and critical understanding of the reasons behind, and the current trajectory of, China's AI strategy. It emphasises that the Chinese government is aware of the potential benefits, practical risks, and the ethical challenges that AI presents, and that the direction of China's AI strategy will largely be determined by the interplay of these factors and by the extent to which government's interests may outweigh ethical concerns. Section 5 concludes the paper by summarising the key findings of our analysis.

2 AI legislation in China

Since 2013, China has published several national-level policy documents, which reflect the intention to develop and deploy AI in a variety of sectors. For example, in 2015, the State Council released guidelines on China's 'Internet+' action. It sought to integrate the internet into all elements of the economy and society. The document clearly stated the importance of cultivating emerging AI industries and investing in research and development. In the same year, the 10-year plan 'Made in China 2025' was released, with the aim to transform China into the dominant player in global high-tech manufacturing, including AI (McBride and Chatzky 2019). Another notable example is the Central Committee of the Communist Party of China's (CCP) 13th 5-year plan,[2] published in March 2016. The document mentioned AI as one of the six critical areas for developing the country's emerging industries (CCP 2016), and as an important factor in stimulating economic growth. When read together, these documents indicate that there has been a conscious effort to develop and use AI in China for some time, even before 'the Sputnik moment'. However, prior to 2016, AI was presented merely as one technology among many others, which could be useful in achieving a range of policy goals. This changed with the release of the AIDP.

2.1 The New generation artificial intelligence development plan (AIDP)

Released in July 2017 by the State Council (which is the chief administrative body within China), the 'New Generation Artificial Intelligence Development Plan' (AIDP) acts as a unified document that outlines China's AI policy objectives. Chinese media have referred to it as 'year one of China's AI development strategy' ("China AI Development Report" 2018, p. 63). The overarching aim of the policy, as articulated by the AIDP, is to make China the world centre of AI innovation by 2030, and make AI 'the main driving force for China's industrial upgrading and economic transformation' (AIDP 2017). The AIDP also indicates the importance of using AI in a broader range of sectors, including defence and social welfare, and focuses on the need to develop standards and ethical norms for the use of AI. Altogether, the Plan provides a comprehensive AI strategy and challenges other leading powers in many key areas.

The AIDP delineates three key steps, each of which contains a series of goals, some of which are tightly defined, while others are vaguer. They are summarised as follows and in Fig. 1 below:

1. By 2020, China aims to maintain competitiveness with other major powers and optimise its AI development environment. In monetary terms, China intends to create an AI industry worth more than 150 billion yuan (ca. 21 billion dollars). Lastly, it seeks to establish initial ethical norms, policies, and regulations for vital areas of AI.
2. By 2025, China aims to have achieved a 'major breakthrough' (as stated in the document) in basic AI theory and to be world-leading in some applications ('some technologies and applications achieve a world-leading level'). China also targets an increase in the worth of its core AI industry to over 400 billion yuan (ca. 58 billion dollars), and plans to expand upon, and codify in law, ethical standards for AI.
3. By 2030, China seeks to become the world's innovation centre for AI. By then, growth in the core AI industry is expected to more than double again and be valued at 1 trillion yuan (ca 147 billion dollars), and further upgrades in the laws and standards are also to be expected, to deal with newly emerging challenges.

2.2 Implementing the AIDP

The Plan will be guided by a new AI Strategy Advisory Committee, established in November 2017, and will be coordinated by the Ministry of Science and Technology (MIST),

[2] The 5-year plans are a central pillar in China's economic growth policy (Heilmann and Melton 2013; Hu 2013).

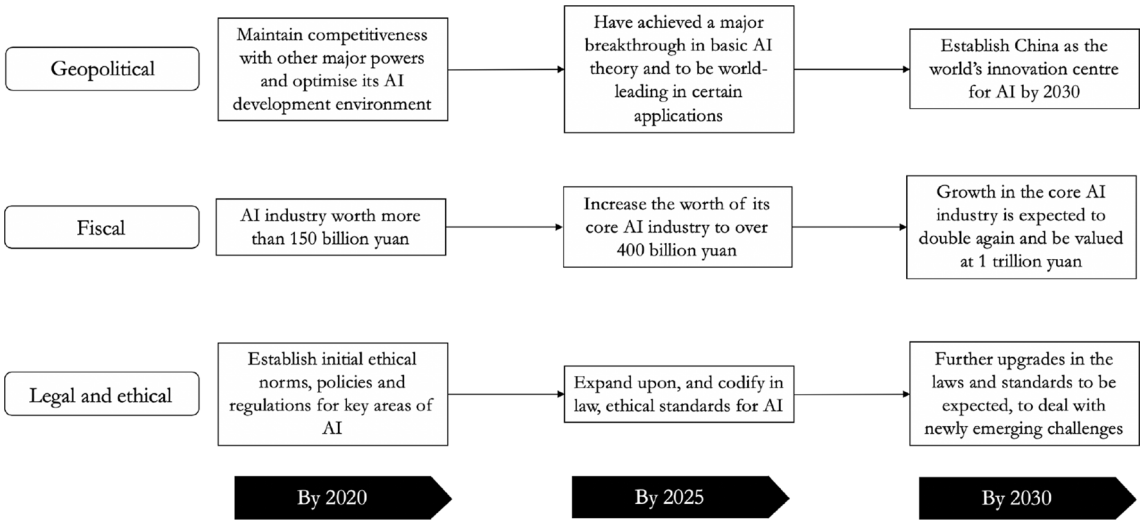

Fig. 1 Visualising China's AIDP

alongside the AI Plan Promotion Office, and other relevant bodies ("AI Policy-China" n.d.).[3] Although these bodies will provide central guidance, the Plan is not meant to act as a centrally enacted initiative. The AIDP instead functions as a stamp of approval for de-risking and actively incentivising local projects that make use of AI. Recognising this point is important: the AIDP is an ambitious strategy set by the central government, but the actual innovation and transformation is expected to be driven by the private sector and local governments. In other words, it is more appropriate to view the AIDP as a highly incentivised 'wish list', to nudge, and coordinate other relevant stakeholders, rather than a central directive (Sheehan 2018). This is why the 3-year plan promoting the AIDP (2018–2020) emphasises coordination between provinces and local governments.

With regard to the private sector, China has selected 'AI national champions': businesses endorsed by the government to focus on developing specific sectors of AI. For example, Baidu has been tasked with the development of autonomous driving, Alibaba with the development of smart cities, and Tencent with computer vision for medical diagnoses (Jing and Dai 2017). Being endorsed as a national champion involves a deal whereby private companies agree to focus on the government's strategic aims. In return, these companies receive preferential contract bidding, easier access to finance, and sometimes market share protection. Although other companies can compete in these fields, historically the status of 'national champion' has helped larger companies dominate their respective sectors (Graceffo 2017).

With this said, the new AI 'national team' differs from previous state-sponsored national champions in that they are already internationally successful in their respective fields, independently of this preferential treatment. Furthermore, there is extensive domestic competition in the areas where national champions have been selected. This suggests that competition may not be stymied in the traditional manner. For instance, all the companies selected as AI national champions are developing technologies in Alibaba's designated area of smart cities (Ding 2019). In parallel with this, patronage does not prohibit smaller companies benefiting from the financial incentive structure. Technology start-ups within China often receive government support and subsidies for developing AI technologies. As an example, Zhongguancun Innovation Town is a purpose-built, government subsidised, incubator workspace that provides a suite of services to help Chinese technology start-ups succeed, often in the sectors where national champions have been selected. Finally, there are also cases where there is no specific endorsement. For example, while the AIDP promotes smart courts, with a stated desire to develop AI for evidence collection, case analysis, and legal document reading, as of April 2020 there is no national champion selected for developing AI applications for the administration of justice.

Concerning local governments, the political structure within China creates a system of incentives for fulfilling national government policy aims. Short term limits for provincial politicians and promotions based on economic performance provide strong incentives for following centrally-defined government initiatives (Li and Zhou 2005; Persson and Zhuravskaya 2016). Thus, local governments become hotbeds for testing and developing central government

[3] It should be noted that, although MIST has been tasked with coordinating the AIDP, it was the Ministry of Industry and Information Technology (MIIT) that released the guidance for the implementing the first step of the AIDP.

policy. The strength of this incentive system can be seen in the decision made by the administration of the city of Tianjin to establish a $5 billion fund for the development of AI, around the same time as the publication of the AIDP (Mozur 2017). At the same time, it is important to recognise how the absence of an effective accountability review of local government spending creates problems within this system. Notably, it has facilitated a mindset in which local politicians know that the central government will bail them out for failed projects, leading to poor budget management (Ji 2014). A clear example of this is the large-scale port building initiatives developed by provincial governments in East coast provinces that were based more on prestige than any economic rationale, and which led to overcapacity and disorderly competition (Zhu 2019).

These incentive structures contain a subtle distinction. A national team has been selected to lead the research and development in a handful of designated strategic areas. Beyond these selected companies, there are few specific guidelines provided to industry and local state agents as to which items to pursue on the AIDP's 'wish list'. This enables companies to cherry-pick the technologies they want to develop and provides local governments with a choice of private sector partners for integrating AI into city infrastructure or governance (Sheehan 2018). Subsequent documentation has emphasised the importance of strengthening organisation and implementation,[4] including between provinces and ministries, yet it is unclear how this coordination would function in practice. Thus, the AIDP may work as a 'wish list', but the exact guidance, incentivisation and risk differ depending on the type of stakeholder.

The AIDP should not be read in isolation when considering China's AI strategy (Ding 2018), but it does provide the most transparent and influential indication of the driving forces behind China's AI strategy. Because of the AIDP's significance (in terms of policy) and importance (in terms of strategy), in the rest of this article, we shall use it as the organisational skeleton for explaining the drivers and ethical boundaries shaping China's approach to AI.

3 China's AI strategic focus

The AIDP provides a longitudinal perspective on China's strategic situation regarding AI, including its comparative capabilities, the opportunities offered, and the potential risks. Following a technology-first approach, it may be tempting to concentrate one's attention on the stated capabilities of AI, to gain an insight into the types of technologies in which China is investing. However, this would likely offer only a short-term perspective and would soon be out of date as technological innovation advances rapidly. Furthermore, it would do little to explain why China is seeking to develop a strong AI sector in the decades to come. To this end, it is more useful to try to understand China's strategic focus from a policy-first approach, by analysing the areas where China considers that AI presents opportunities. In this section, we focus on these areas of particular importance to China, on how and what China expects to gain from developing AI in each of them, and on some of the perceived risks present in each of these areas. The AIDP highlights three areas where AI can make a substantial difference within China: international competition, economic development, and social governance. They are strictly interrelated but, for the sake of clarity, we shall analyse them separately, and contextualise each of them by discussing the relevant literature surrounding the broader political backdrop and contemporary policy debates.

3.1 International competition

The AIDP states that AI has become a new focus of international competition and that 'the development of AI [is] […] a major strategy to enhance national competitiveness and protect national security' (AIDP 2017). It emphasises that China should take the strategic opportunity afforded by AI to make 'leapfrog developments'[5] in military capabilities. Although China and the US are regularly portrayed as geopolitical rivals (Mearsheimer 2010; Zhao 2015), the military budgets of the two powers remain significantly different. China has the world's second-largest military budget, with $175 billion allocated in 2019 (Chan and Zhen 2019), but its spending is still only a third of the US budget (Martina and Blanchard 2019). Rather than outspending the US in conventional weaponry, China considers investing in AI as an opportunity to make radical breakthroughs in military technologies and thus overtake the US.

Attempts to use technologies to challenge US hegemony are nothing new within China's military strategy. Since the late 1990s, the country has been following a policy of 'shashoujian' (杀手锏), which roughly translates as 'trump-card' (Bruzdzinski 2004). Rather than directly competing with the US, China has sought to develop asymmetric capabilities, which could provide a critical advantage in warfare

[4] To accompany the three steps outlined earlier, the Ministry of Industry and Information Technology (MIIT) provides documents to flesh out these aims. The first of these, 'Three-Year Action Plan for Promoting Development of a New Generation Artificial Intelligence Industry (2018–2020)', has already been released.

[5] 'This term refers to 'an actor, which lags behind its competitors in terms of development, coming up with a radical innovation that will allow it to overtake its rivals' (Brezis et al. 1993).'

and credible deterrence in peacetime (Blasko 2011). This trump-card strategy seeks to use unorthodox technologies against enemies' weaknesses to gain the initiative in war (Peng and Yao 2005). The trump-card approach was echoed by the former Party Chairman, Jiang Zemin, who emphasised that technology should be the foremost focus of the military, especially the technology that the 'enemy fears [the] most' (Cheung et al. 2016).

One area in which China has been developing these asymmetric tactics is cyber warfare, where capabilities have been developed for targeting the US military's battle-critical networks if needed (Kania 2017a). Alongside this, evidence points to the persistent use of cyberattacks to collect scientific, technological and commercial intelligence (Inkster 2010). The Chinese position on these capabilities is ambivalent. On the one hand, China has officially promoted international initiatives for regulating hostile state-run activities in cyberspace, and to fill the existing regulatory gap for state behaviour in this domain (Ku 2017; Austin 2016; Taddeo 2012; Taddeo 2016). For example, China co-sponsored the International Code of Conduct for Information Security at the UN General Assembly in September 2011, which sought a commitment against using information technologies in acts of aggression and has provided continued support for dialogue by the UN Group of Government Experts in preventing cyber conflicts (Meyer 2020). On the other hand, China has also run cyber operations targeting US infrastructure and aiming at extracting commercial and scientific information as well as acquiring relevant intelligence against several countries, including Australia, Philippines, Hong Kong, and the US.[6]

The desire to leapfrog the US is echoed in statements from China's political and military leadership. For instance, President Xi Jinping stated in 2017 that 'under a situation of increasingly fierce international military competition, only the innovators win' (Kania 2020, p. 2). This sentiment is shared by Lieutenant General Liu Guozhi, deputy of the 19th National Congress and director of the Science and Technology Committee of the Central Military Commission, who stated in an interview that AI presented a rare opportunity for taking shortcuts to achieve innovation and surpass rivals ("AI military reform" 2017). In parallel, academics affiliated with the People's Liberation Army (PLA) highlight that AI will be used to predict battlefield situations and identify optimal approaches, facilitating 'winning before the war' (Li 2019). Some members of the PLA go further than this in anticipating a battlefield 'singularity', where AI outpaces human decision-making (Kania 2017a). These statements emphasise the belief, which is widespread throughout China's military and defence circles, in the importance of utilising emergent technologies including AI to achieve a competitive military advantage.

As China has developed economically and militarily, the focus of the country's military strategy has also matured. Over the past few years, China's strategy has coalesced around efforts to develop 'new concept weapons' to surpass the US's military capabilities. These are not limited to AI alone, and are applicable to China's investments in other fields of emerging military technologies, like hypersonic weaponry (Kania 2017b). Therefore, China's efforts to use technology to gain an advantage in military affairs should not be seen as something new, but instead understood within a broader historical context of finding innovative ways to challenge the hegemony of the US.

Although the push for leapfrog developments marks a continuation of previous policy, there are strong concurrent indications that Chinese officials are also concerned about AI causing an arms race and potential military escalation. Statements of senior officials seem to suggest a belief in cooperation and arms control to mitigate the risks that AI's military development poses. In particular, three major risks are central to the debate:

(i) human involvement and control once AI-based weapons are deployed;
(ii) the absence of well-defined norms for state behaviour and use of AI weapons, which in turn increases;
(iii) the likelihood of misperceptions or unintentional conflict escalation (Taddeo and Floridi 2018; Allen 2019).

These concerns underpin China's support to restrict the use of autonomous weapons, as expressed at the 5th Convention on Certain Conventional Weapons ("Chinese Position Paper" 2016) and, more recently, the desire to ban autonomous lethal weapons (Kania 2018a). Despite concerns (i)–(iii), it is crucial to stress that China is the actor pursuing the most aggressive strategy for developing AI for military uses among the major military powers (Pecotic 2019).

Digging more deeply into China's actions on the international stage is revealing. The ban that China advocated encompassed only usage and not the development or production of autonomous lethal weapon systems. Thus, it would not prevent the existence of autonomous lethal weapons serving as a deterrent, in much the same way that China has a putative 'no first use' (NFU) doctrine for nuclear weapons. Furthermore, the definition of autonomy embraced by China is extremely narrow, including only fully autonomous weapons ("UN Seeks Human Control Over Force" 2018). Some commentators argue that this juxtaposition of cautious concerns about deployment, on the one hand, and an aggressive approach to development, on the other, can be explained

[6] https://www.csis.org/programs/technology-policy-program/significant-cyber-incidents.

by the Chinese efforts to exert pressure on other militaries whose democratic societies are more sensitive to the controversies of using automated weapons (Kania 2018a). This is a reasonable claim: a continuation of propaganda may be part of the explanation. For instance, China was the first nuclear power to pledge 'no first use' of nuclear weapons (so far only India has a similar pledge; other countries, including the US and the UK, have pledged to use nuclear weapons only defensively). But rather than offering a genuine commitment to NFU, this pledge was meant as internal and external propaganda tool, which would be circumvented by semantics if needed (Schneider 2009).

Taken together, China's focus on military AI can be considered as a continuation of a longer-term strategy, which privileges developing (with the threat of deploying) technology to gain a military advantage. There remains a conscious recognition, by several actors in China, that developing AI presents an especially fraught risk of igniting an arms race or causing unintentional escalation due to the autonomy of these technologies (Taddeo and Floridi 2018; Allen 2019). But at the political level, efforts to curtail the use of military AI internationally may also be seen as part of a propaganda strategy.

3.2 Economic development

Economic development is the second strategic opportunity explicitly mentioned in the AIDP. It is stated that AI will be the driving force behind a new round of industrial transformation, which will 'inject new kinetic energy into China's economic growth' (AIDP 2017). The reconstruction of economic activity is targeted in all sectors, with manufacturing, agriculture, logistics, and finance being the examples promoted in the AIDP.

China's rapid growth has frequently been referred to as an 'economic miracle', due to the country's shift from having a slow-growth economy to enjoying some of the world's highest growth rates for almost three decades (Ray 2002; Naughton and Tsai 2015). A number of factors facilitated this economic growth, of which the demographic dividend is one. A large workforce, in combination with a small dependent population, fostered high levels of savings and heavy investment (Cai and Lu 2013). Structural changes, including a conscious shift from a predominantly agricultural to a manufacturing economy, and the opening up of markets, are additional, critical factors. By 2012, China's labour force growth dropped to around zero, and its shift from an agricultural to a manufacturing economy had largely matured. These trends have led Chinese policymakers to the realisation that an alternative development model is necessary for maintaining high rates of growth. This model rests on the shift from heavy investment in the industry to growth stimulated by an innovative society (Naughton and Tsai 2015). Recently, science and technology have been put forward as a crucial means for achieving this type of innovative growth (Zhang 2018).

Some commentators have argued that maintaining these high levels of growth is particularly important for China due to the implicit trading by citizens of political freedoms for economic growth and embourgeoisement (Balding 2019). Research has highlighted that support for the party and a relatively lackluster desire for democracy stems from satisfaction with employment and material aspects of life, particularly within the middle classes (Chen 2013). Slowing economic growth would likely sow dissatisfaction within the populace and make inherent features within the Chinese political system, such as corruption, less tolerable (Diamond 2003; Pei 2015). A lack of a democratic outlet for this frustration could lower the overall support that the government currently receives. Some maintain that this creates a 'democratise or die' dynamic (Huang 2013), however, this may be unfeasible, given China's political control (Dickson 2003; Chin 2018).

Against this backdrop, a report by PwC suggested that China is the country that has the most to gain from AI, with a boost in GDP of up to 26% by 2030 ("Sizing the Prize" 2017). Estimates also suggest that AI could facilitate an increase in employment by 12% over the next two decades ("Net Impact of AI on Jobs in China?" 2018). Because of these potential benefits, President Xi has frequently spoken of the centrality of AI to the country's overall economic development (Hickert and Ding 2018; Kania 2018b). China has been pursuing the potential economic benefits of AI concretely and proactively for some time. For example, there has been a 500% increase in the annual installation of robotic upgrades since 2012. This rate is staggering, especially when compared to a rate of just over 100% in Europe (Shoham et al. 2018), equating to over double the number of robot installations in China than Europe.

AI can be a double-edged sword, because the benefits and improvements brought about by AI come with the risk, amongst others, of labour market disruptions. This is a concern explicitly stated in the AIDP. Although the aforementioned PwC report predicts that automation will increase the net number of jobs in China, disruption will likely be unevenly spread ("Net Impact of AI on Jobs in China?" 2018). Smarter automation will most immediately affect low- and medium-skilled jobs while creating opportunities for higher-skilled technical roles (Barton et al. 2017). China has been active in its efforts to adapt to such AI-related risks, especially with an education overhaul promoted by the 'National Medium- and Long-term Education Reform and Development Plan (2010–2020)'. This plan has the goal of supporting the skilled labour required in the information age ("Is China Ready for Intelligent Automation" 2018). In

the same vein, China is addressing the shortage in AI skills specifically by offering higher education courses on the subject (Fang 2019). Accordingly, China seems to be preparing better than other middle-income countries to deal with the longer-term challenges of automation ("Who is Ready for Automation?" 2018).

Although these efforts will help to develop the skill set required in the medium and long term, they do little to ease the short-term structural changes. Estimates show that, by 2030, automation in manufacturing might have displaced a fifth of all jobs in the sector, equating to 100 million workers ("Is China Ready for Intelligent Automation" 2018). These changes are already underway, with robots having replaced up to 40% of workers in several companies in China's export-manufacturing provinces of Zhejiang, Jiangsu and Guangdong (Yang and Liu 2018). In the southern city of Dongguan alone, reports suggest that 200,000 workers have been replaced with robots ("Is China Ready for Intelligent Automation" 2018). When this is combined with China's low international ranking in workforce transition programmes for vocational training ("Is China Ready for Intelligent Automation" 2018), it can be suggested that the short-term consequence of an AI-led transformation is likely to be significant disruptions to the workforce, potentially exacerbating China's growing inequality (Barton et al. 2017).

3.3 Social governance

Social governance, or more literally in Chinese 'social construction',[7] is the third area in which AI is promoted as a strategic opportunity for China. Alongside an economic slowdown, China is facing emerging social challenges, hindering its pursuit of becoming a 'moderately prosperous society' (AIDP 2017). An aging population and constraints on the environment and other resources are explicit examples provided in the AIDP of the societal problems that China is facing. Thus, the AIDP outlines the goal of using AI within a variety of public services to make the governance of social services more precise and, in doing so, mitigate these challenges and improve people's lives.

China has experienced some of the most rapid structural changes of any country in the past 40 years. It has been shifting from a planned to a market economy and from a rural to an urban society (Naughton 2007). These changes have helped facilitate economic development, but also introduced a number of social issues. One of the most pressing social challenges China is facing is the absence of a well-established welfare system (Wong 2005). Under the planned economy, workers were guaranteed cradle-to-grave benefits, including employment security and welfare benefits, which were provided through local state enterprises or rural collectives (Selden and You 1997). China's move towards a socialist market economy since the 1990s has accelerated a shift of these provisions from enterprises and local collectives to state and societal agencies (Ringen and Ngok 2017). In practice, China has struggled to develop mature pension and health insurance programmes, creating gaps in the social safety net (Naughton 2007). Although several initiatives have been introduced to alleviate these issues (Li et al. 2013), the country has found it difficult to implement them (Ringen and Ngok 2017).

The serious environmental degradation that has taken place in the course of China's rapid development is another element of concern. For most of China's development period, the focus has been on economic growth, with little or no incentive provided for environmental protection (Rozelle et al. 1997). As a result, significant, negative externalities and several human-induced natural disasters have occurred that have proven detrimental for society. One of the most notable is very poor air quality, which has been linked to an increased chance of illness and is now the fourth leading cause of death in China (Delang 2016). In parallel, 40% of China's rivers are polluted by industry, causing 60,000 premature deaths per year (Economy 2013). Environmental degradation of this magnitude damages the health of the population, lowers the quality of life, and places further strain on existing welfare infrastructure.

The centrality of these concerns could be seen at the 19th National Party Congress in 2017, where President Xi declared that the 'principal contradiction' in China had changed. Although the previous 'contradiction' focused on 'the ever-growing material and cultural needs of the people and backward social production,' Xi stated 'what we now face is the contradiction between unbalanced and inadequate development and the people's ever-growing needs for a better life' (Meng 2017). After years of focusing on untempered economic growth, President Xi's remarks emphasise a broader shift in China's approach to dealing with the consequences of economic liberalisation.

These statements are mirrored in several government plans, including the State Council Initiative, 'Healthy China 2030', which seeks to overhaul the healthcare system. Similar trends can be seen in China's efforts to clean up its environment, with a new 3-year plan building on previous relevant initiatives (Leng 2018). China has recently focused on AI as a way of overcoming these problems and improving the welfare of citizens. It has been pointed out that China's major development strategies rely on solutions driven by big data (Heilmann 2017). For example, 'Healthy China 2030' explicitly stresses the importance of technology in achieving China's healthcare reform strategy, and emphasises a

[7] The Chinese text (社会建设) directly translates to 'society/community' and 'build/construction'.

switch from treatment to prevention, with AI development as a means to achieve the goal (Ho 2018). This approach also shapes environmental protection, where President Xi has been promoting 'digital environmental protection' (数字环保) (Kostka and Zhang 2018). Within this, AI is being used to predict and mitigate air pollution levels (Knight 2015), and to improve waste management and sorting ("AI-powered waste management underway in China" 2019).

The administration of justice is another area where the Chinese government has been advancing using AI to improve social governance. Under Xi Jinping, there has been an explicit aim to professionalise the legal system, which suffers from a lack of transparency, issues of local protectionism, and interference in court cases by local officials (Finder 2015). A variety of reforms have been introduced in an attempt to curtail these practices including, transferring responsibility for the management of local courts from local to provincial governments, the creation of a database where judges can report attempts at interference by local politicians, and a case registration system that makes it more difficult for courts to reject complex or contentious cases (Li 2016).

Of particular interest, when focusing on AI, is the 'Several Opinions of the Supreme People's Court on Improving the Judicial Accountability System' (2015), which requires judges to reference similar cases in their judicial reasoning. Furthermore, it stipulates that decisions conflicting with previous similar cases should trigger a supervision mechanism with more senior judges. To help judges minimise inconsistencies, an effort has been made to introduce AI technologies that facilitate making 'similar judgements in similar cases' (Yu and Du 2019). In terms of technology, two overarching types of systems have emerged. The first is a 'similar cases pushing system', where AI is used to identify judgements from similar cases and provide judges these for reference. This type of system has been introduced by, amongst others, Hainan's High People's Court who has also encouraged the use of AI systems in lower-level courts across the province (Yuan 2019). The second type uses AI techniques to provide an 'abnormal judgement warning' that would detect if a judgement made differs from similar cases. If an inconsistent judgement does occur, the system alerts the judge's superiors, prompting an intervention. Despite the potential that AI-assisted sentencing holds for reducing the workload of judges and lessening corruption, feedback from those who have used the systems suggests that the technology is currently too imprecise (Yu and Du 2019). Some legal theorists have gone further in their criticism, highlighting the inhumane effects of using technology in sentencing and the detriment that it could cause for 'legal hermeneutics, legal reasoning techniques, professional training and the ethical personality of the adjudicator' (Ji 2013, p. 205).

Looking forward, the focus on China's use of AI in governance seems most likely to centre on the widely reported 'Social Credit' System, which is premised upon developing the tools required to address China's pressing social problems (Chorzempa et al. 2018). To do this, the system broadly aims at increasing the state's governance capacity, promoting the credibility of state institutions, and building a viable financial credit base (Chai 2018). Currently, 'the' Social Credit System is not one unified nationwide system but rather comprises national blacklists that collate data from different government agencies, individual social credit systems run by local governments, and private company initiatives (Liu 2019). These systems are fractious and, in many cases, the local trials lack technical sophistication, with some versions relying on little more than paper and pen (Gan 2019). Nonetheless, the ambitious targets of the Social Credit System provide a compelling example of the government's intent to rely on digital technology for social governance and also for more fine-grained regulation of the behaviour of its citizens.

3.4 Moral governance

Social governance/construction in China does not just encompass material and environmental features, but also the behaviour of citizens. Scholars have argued that the disruption of the Maoist period followed by an 'opening up' has created a moral vacuum within China (Yan 2009; Lazarus 2016). These concerns are echoed by the Chinese public, with Ipsos Mori finding that concerns over 'moral decline' in China were twice as high as the global average (Atkinson and Skinner 2019).[8] This is something that has been recognised by the Chinese government, with high-level officials, including President Xi, forwarding the idea of a 'minimum moral standard' within society (He 2015). This goal is not limited to ensuring 'good' governance in the traditional sense; it extends to the regulating the behaviour of citizens and enhancing their moral integrity, which is considered a task within the government's remit ("Xi Jinping's report at 19th CPC National Congress" 2017). In view of the government, AI can be used to this end.

The AIDP highlights AI's potential for understanding group cognition and psychology (2017). The intention to rely on AI for moral governance can be seen in further legislation, with perhaps the clearest example being the State Council's 'Outline for the Establishment of a Social Credit System', released in 2014. This document underscored that

[8] It is worth highlighting, however, that the Chinese are more than double the world average, and ranked first, when it comes to answering the question "whether the country is going in the right direction", with 94% of the respondents in agreement.

the Social Credit System did not just aim to regulate financial and corporate actions of business and citizens, but also the social behaviour of individuals. This document outlines several social challenges that the plan seeks to alleviate, including tax evasion, food safety scares, and academic dishonesty (Chorzempa et al. 2018). As highlighted, current efforts to implement these systems have been fractious, yet a number have already included moral elements, such as publicly shaming bad debtors (Hornby 2019).

Further concrete examples of how China has been utilising AI in social governance can be seen in the sphere of internal security and policing. China has been at the forefront of the development of smart cities, with approximately half of the world's smart cities located within China. The majority of resources that have gone into developing these cities have focused on surveillance technologies, such as facial recognition and cloud computing for ordinary policing (Anderlini 2019). The use of advanced 'counterterrorism'[9] surveillance programmes in the autonomous region of Xinjiang offers clearer and more problematic evidence of governmental efforts to use AI for internal surveillance. This technology is not limited to facial recognition, but also includes mobile phone applications to track the local Uyghur population, who are portrayed by the government as potential dissidents or terrorists ("China's Algorithms of Repression" 2019). When government statements are read in parallel with these developments, it seems likely that some form of the Social Credit System(s) will play a central role in the future of China's AI-enabled governance (Ding 2018), putting the rights of citizens under a sharp devaluative pressure. For example, most citizens generate large data footprints, and nearly all day-to-day transactions in cities are cashless and done with mobile apps (Morris 2019), internet providers enact 'real-name registration', linking all online activity to the individual (Sonnad 2017), enabling the government to identify and have access to the digital profile of all citizens using mobile-internet services.

The significant and likely risks related to implementing AI for governance stem from the intertwining of the material aspects of social governance with surveillance and moral control. Articles in the Western media often emphasise the problematic nature of 'the' Social Credit System, due to the authoritarian undertones of this pervasive control (Clover 2016; Botsman 2017). Examples of public dissatisfaction with specific features of locally run social credit systems appear to support this viewpoint (Zhang and Han 2019). In some cases, there have even been cases of public backlash leading to revisions in the rating criteria for local social credit systems. In contrast, some commentators have emphasised that, domestically, a national social credit system may be positively received as a response to the perception of moral decline in China, and a concomitant desire to build greater trust; indeed, it has been suggested that the system may be better named the 'Social Trust' system (Song 2018; Kobie 2019). When looking at the punishments distributed by social credit systems, some measures, including blacklisting citizens from travelling due to poor behaviour on trains, have received a positive response on Chinese social media. Government censorship and a chilling effect could account for this support, but there is currently no evidence of censors specifically targeting posts concerning social credit systems (Koetse 2018).

Efforts have also been made to understand public opinion on the systems as a whole, rather than just specific controversies or cases of blacklisting. A nationwide survey by a Western academic on China's social credit systems found high levels of approval within the population (Kostka 2019). With this said, problems with the methodology of the paper, in particular with the translation of 'social credit system', indicate that it may be more appropriate to consider a general lack of awareness, rather than a widespread sentiment of support ('Beyond Black Mirror' 2019). These points indicate that it is too early to measure public sentiment in China surrounding the development of the Social Credit System(s).

It is important to recognise that despite the relative mundanity of current applications of the Social Credit System (Daum 2019; Lewis 2019), looking forward, substantial ethical risks and challenges remain in relation to the criteria for inclusion on a blacklist or receiving a low score and the exclusion that this could cause. In terms of the former, national blacklists are comprised of those who have broken existing laws and regulations, with a clear rationale for inclusion provided (Engelmann et al. 2019). However, the legal documents on which these lists are built are often ill-defined and function within a legal system that is subordinate to the Chinese Communist Party (Whiting 2017). As a result, legislation, like the one prohibiting the spread of information that seriously disturbs the social order, could be used to punish individuals for politically undesirable actions, including free speech (Arsène 2019). Still, it is more appropriate to consider this a problem of the political-legal structure and not a social credit system per se. The fundamental, ethical issue of an unacceptable approach to surveillance remains unaddressed.

In relation to local score-based systems that do not solely rely on illegality, assessment criteria can be even vaguer. For instance, social credit scores in Fuzhou account for 'employment strength', which is based on the loosely defined 'hard-working/conscientious and meticulous' (Lewis 2019). This is ethically problematic because of the opaque and arbitrary inclusion standards that are introduced for providing people

[9] The word 'counterterrorism' started to be used after 9/11, with the phrase 'cultural integration' favoured before this ("Devastating Blows 2005).

certain benefits. In tandem with inclusion is the exclusion that punishments from these systems can cause. At present, most social credit systems are controlled by separate entities and do not connect with each other (Liu 2019), limiting excessive punishment and social exclusion. Nonetheless, memorandums of understanding are emerging between social credit systems and private companies for excluding those blacklisted from activities such as flying (Arsène 2019). As a result, it is important to emphasise that whilst the Social Credit System(s) is still evolving, the inclusion criteria and potential exclusion caused raise serious ethical questions.

4 The debate on digital ethics and AI in China

Alongside establishing material goals, the AIDP outlines a specific desire for China to become a world leader in defining ethical norms and standards for AI. Following the release of the AIDP, the government, public bodies, and industry within China were relatively slow to develop AI ethics frameworks (Lee 2018; Hickert and Ding 2018). However, there has been a recent surge in attempts to define ethical principles. In March 2019, China's Ministry of Science and Technology established the National New Generation Artificial Intelligence Governance Expert Committee. In June 2019, this body released eight principles for the governance of AI. The principles emphasised that, above all else, AI development should begin from enhancing the common well-being of humanity. Respect for human rights, privacy and fairness were also underscored within the principles. Finally, they highlighted the importance of transparency, responsibility, collaboration, and agility to deal with new and emerging risks (Laskai and Webster 2019).

In line with this publication, the Standardization Administration of the People's Republic of China, the national-level body responsible for developing technical standards, released a white paper on AI standards. The paper contains a discussion of the safety and ethical issues related to technology (Ding and Triolo 2018). Three key principles for setting the ethical requirements of AI technologies are outlined. First, the principle of human interest states that the ultimate goal of AI is to benefit human welfare. Second, the principle of liability emphasises the need to establish accountability as a requirement for both the development and the deployment of AI systems and solutions. Subsumed within this principle is transparency, which supports the requirement of understanding what the operating principles of an AI system are. Third, the principle of consistency *of* [sic] rights and responsibilities emphasised that, on the one hand, data should be properly recorded and oversight present but, on the other hand, that commercial entities should be able to protect their intellectual property (Ding and Triolo 2018).

Government affiliated bodies and private companies have also developed their own AI ethics principles. For example, the Beijing Academy of Artificial Intelligence, a research and development body including China's leading companies and Beijing universities, was established in November 2018 (Knight 2019). This body then released the 'Beijing AI Principles' to be followed for the research and development, use, and governance of AI ("Beijing AI Principles" 2019). Similar to the principles forwarded by the AIDP Expert Committee, the Beijing Principles focus on doing good for humanity, using AI 'properly', and having the foresight to predict and adapt to future threats. In the private sector, one of the most high-profile ethical framework has come from the CEO of Tencent, Pony Ma. This framework emphasises the importance of AI being available, reliable, comprehensible, and controllable (Si 2019). Finally, the Chinese Association for Artificial Intelligence (CAII)[10] has yet to establish ethical principles but did form an AI ethics committee in mid-2018 with this purpose in mind ("AI association to draft ethics guidelines" 2019).

The aforementioned principles bear some similarity to those supported in the Global North (Floridi and Cowls 2019), yet institutional and cultural differences mean that the outcome is likely to be significantly different. China's AI ethics needs to be understood in terms of the country's culture, ideology, and public opinion (Triolo and Webster 2017). Although a full comparative analysis is beyond the scope of this article, it might be anticipated, for example, that the principles which emerge from China place a greater emphasis on social responsibility and group and community relations, with relatively less focus on individualistic rights, thus echoing earlier discussions about Confucian ethics on social media (Wong 2013).

In the following sections, we shall focus on the debate about AI ethics as it is emerging in connection with privacy and medical ethics because these are two of the most mature areas where one may grasp a more general sense of the current 'Chinese approach' to digital ethics. The analysis of the two areas is not meant to provide an exhaustive map of all the debates about ethical concerns over AI in China. Instead, it may serve to highlight some of the contentious issues that are emerging, and inform a wider understanding of the type of boundaries which may be drawn in China when a normative agenda in the country is set.

[10] The Chinese Association for Artificial Intelligence (CAAI) is the only state-level science and technology organization in the field of artificial intelligence under the Ministry of Civil Affairs.

4.1 Privacy

All of the sets of principles for ethical AI outlined above mention the importance of protecting privacy. However, there is a contentious debate within China over exactly what types of data should be protected. China has historically had weak data protection regulations—which has allowed for the collection and sharing of enormous amounts of personal information by public and private actors—and little protection for individual privacy. In 2018, Robin Li, co-founder of Baidu, stated that 'the Chinese people are more open or less sensitive about the privacy issue. If they are able to trade privacy for convenience, safety and efficiency, in a lot of cases, they are willing to do that' (Liang 2018). This viewpoint—which is compatible with the apparently not too negative responses to the Social Credit System—has led some Western commentators to misconstrue public perceptions of privacy in their evaluations of China's AI strategy (Webb 2019). However, Li's understanding of privacy is not one that is widely shared, and his remarks sparked a fierce backlash on Chinese social media (Liang 2018). This concern for privacy is reflective of survey data from the Internet Society of China, with 54% of respondents stating that they considered the problem of personal data breaches as 'severe' (Sun 2018). When considering some cases of data misuse, this number is unsurprising. For example, a China Consumers Association survey revealed that 85% of people had experienced a data leak of some kind (Yang 2018). Thus, contrary to what may be inferred from some high-profile statements, there is a general sentiment of concern within the Chinese public over the misuse of personal information.

As a response to these serious concerns, China has been implementing privacy protection measures, leading one commentator to refer to the country as 'Asia's surprise leader on data protection' (Lucas 2018). At the heart of this effort has been the Personal Information Security Specification (the Specification), a privacy standard released in May 2018. This standard was meant to elaborate on the broader privacy rules, which were established in the 2017 Cyber Security Law. In particular, it focused on both protecting personal data and ensuring that people are empowered to control their own information (Hong 2018). A number of the provisions within the standard were particularly all-encompassing, including a broad definition of sensitive personal information, which includes features such as reputational damage. The language used in the standard led one commentator to argue that some of the provisions were more onerous than those of the European Union's (EU) General Data Protection Regulation (GDPR) (Sacks 2018).

Despite the previous evidence, the nature of the standard means that it is not really comparable to the GDPR. On the one hand, rather than being a piece of formally enforceable legislation, the Specification is merely a 'voluntary' national standard created by the China National Information Security Standardization Technical Committee (TC260). It is on this basis that one of the drafters stated that this standard was not comparable to the GDPR, as it is only meant as a guiding accompaniment to previous data protection legislation, such as the 2017 Cyber Security law (Hong 2018). On the other hand, there remains a tension that is difficult to resolve because, although it is true that standards are only voluntary, standards in China hold substantive clout for enforcing government policy aims, often through certification schemes (Sacks and Li 2018). In June 2018, a certification standard for privacy measures was established, with companies such as Alipay and Tencent Cloud receiving certification (Zhang and Yin 2019). Further, the Specification stipulates the specificities of the enforceable Cybersecurity Law, with Baidu and AliPay both forced to overhaul their data policies due to not 'complying with the spirit of the Personal Information Security Standard' (Yang 2019).

In reality, the weakness in China's privacy legislation is due less to its 'non-legally binding' status and more to the many loopholes in it, the weakness of China's judicial system, and the influential power of the government, which is often the last authority, not held accountable through democratic mechanisms. In particular, significant and problematic exemptions are present for the collection and use of data, including when related to security, health, or the vague and flexibly interpretable 'significant public interests'. It is these large loopholes that are most revealing of China's data policy. It may be argued that some broad consumer protections are present, but actually this is not extended to the government (Sacks and Laskai 2019). Thus, the strength of privacy protection is likely to be determined by the government's decisions surrounding data collection and usage, rather than legal and practical constraints. This is alarming.

It is important to recognise that the GDPR contains a similar 'public interest' basis for lawfully processing personal data where consent or anonymisation are impractical and that these conditions are poorly defined in legislation and often neglected in practice (Stevens 2017). But the crucial and stark difference between the Chinese and EU examples concerns the legal systems underpinning the two approaches. The EU's judicial branch has substantive influence, including the capacity to interpret legislation and to use judicial review mechanisms to determine the permissibility of legislation more broadly.[11] In contrast, according to the Chinese legal system, the judiciary is subject to supervision and interference from the legislature, which has de jure legislative supremacy (Ji 2014); this gives de facto

[11] As a practical example of this, the Court of Justice of the European Union gave judgment in Rīgas Case (2017) that has been used in defining what is meant by 'legitimate interest.'.

control to the Party (Horsley 2019). Thus, the strength of privacy protections in China may be and often is determined by the government's decisions surrounding data collection and usage rather than legal and practical constraints. As it has been remarked, 'The function of law in governing society has been acknowledged since 2002, but it has not been regarded as essential for the CCP. Rather, morality and public opinion concurrently serve as two alternatives to the law for the purpose of governance. As a result, administrative agencies may ignore the law on the basis of party policy, morality, public opinion, or other political considerations' (Wang and Liu 2019, p. 6).

When relating this back to AI policy, China has benefited from the abundance of data that historically lax privacy protections have facilitated (Ding 2018). On the surface, China's privacy legislation seems to contradict other development commitments, such as the Social Credit System, which requires extensive personal data. This situation creates a dual ecosystem whereby the government is increasingly willing to collect masses of data, respecting no privacy, while simultaneously admonishing tech companies for the measures they employ (Sacks and Laskai 2019). Recall that private companies, such as the AI National Team, are relied upon for governance at both a national and local level, and therefore may receive tacit endorsement rather than admonishment in cases where the government's interests are directly served. As a result, the 'privacy strategy' within China appears to aim to protect the privacy of a specific type of consumer, rather than that of citizens as a whole, allowing the government to collect personal data wherever and whenever it may be merely useful (not even strictly necessary) for its policies. From an internal perspective, one may remark that, when viewed against a backdrop of high levels of trust in the government and frequent private sector leaks and misuses, this trade-off seems more intelligible to the Chinese population. The Specification has substantial scope for revising this duality, with a number of loopholes being closed since the initial release (Zhang and Yin 2019), but it seems unlikely that privacy protections from government intrusion will be codified in the near future. The ethical problem remains unresolved.

4.2 Medical ethics

Medical ethics is another significant area impacted by the Chinese approach to AI ethics. China's National Health Guiding Principles have been central to the strategic development and governance of its national healthcare system for the past 60 years (Zhang and Liang 2018). They have been re-written several times, as the healthcare system has transitioned from being a single-tier system, prior to 1978, to a two-tier system that was reinforced by healthcare reform in 2009 (Wu and Mao 2017). The last re-write of the Guiding Principles was in 1996 and the following principles still stand (Zhang and Liang 2018):

(a) People in rural areas are the top priority
(b) Disease prevention must be placed first
(c) Chinese traditional medicine and Western medicine must work together
(d) Health affairs must depend on science and education
(e) Society as a whole should be mobilised to participate in health affairs, thus contributing to the people's health and the country's overall development.

All five principles are relevant for understanding China's healthcare system as a whole but, from the perspective of analysing the ethics of China's use of AI in the medical domain, principles (a), (b), and (e) are the most important. They highlight that—in contrast to the West, where electronic healthcare data are predominantly focused on individual health, and thus AI techniques are considered crucial to unlock 'personalised medicine' (Nittas et al. 2018)—in China, healthcare is predominantly focused on the health of the population. In this context, the ultimate ambition of AI is to liberate data for public health purposes[12] (Li et al. 2019a, b). This is evident from the AIDP, which outlines the ambition to use AI to 'strengthen epidemic intelligence monitoring, prevention and control,' and to 'achieve breakthroughs in big data analysis, Internet of Things, and other key technologies' for the purpose of strengthening community intelligent health management. The same aspect is even clearer in the State Council's 2016 official notice on the development and use of big data in the healthcare sector, which explicitly states that health and medical big data sets are a national resource and that their development should be seen as a national priority to improve the nation's health (Zhang et al. 2018).[13]

From an ethical analysis perspective, the promotion of healthcare data as a public good throughout public policy—including documents such as Measures on Population Health Information and the Guiding Opinions on Promoting and Regulating the Application of Big Medical and Health Data (Chen and Song 2018)—is crucial. This approach,

[12] This is not to imply that the West is not interested in using AI for population health management purposes, or that China is not interested in using AI for personalised health purposes. China is, for example, also developing an integrated data platform for research into precision medicine (Zhang et al. 2018). We simply mean to highlight that the order of priority between these two goals seems to differ.

[13] The challenges section outlines some concrete benefits of implementing AI, illustrating some perceived gains to China. A separate (though more technological than ethical) point substantiated by the article is there is a lot of medical data which could potentially be beneficial, but the data are spread out among hospitals, not used for research, and largely unstructured.

combined with lax rules about data sharing within China (Liao 2019; Simonite 2019), and the encouragement of the open sharing of public data between government bodies ("Outline for the Promotion of Big Data Development" 2015), promotes the collection and aggregation of health data without the need for individual consent, by positioning group beneficence above individual autonomy. This is best illustrated with an example. As part of China's 'Made in 2025' plan, 130 companies, including 'WeDoctor' (backed by Tencent, one of China's AI national champions) signed co-operation agreements with local governments to provide medical check-ups comprised of blood pressure, electrocardiogram (ECG), urine and blood tests, free of charge to rural citizens (Hawkins 2019). The data generated by these tests were automatically (that is with no consent from the individual) linked to a personal identification number and then uploaded to the WeDoctor cloud, where they were used to train WeDoctor's AI products. These products include the 'auxiliary treatment system for general practice', which is used by village doctors to provide suggested diagnosis and treatments from a database of over 5000 symptoms and 2000 diseases. Arguably, the sensitive nature of the data can make 'companies—and regulators—wary of overseas listings, which would entail greater disclosure and scrutiny' (Lucas 2019). Although this, and other similar practices, do involve anonymisation, they are in stark contrast with the European and US approaches to the use of medical data, which prioritise individual autonomy and privacy, rather than social welfare. A fair balance between individual and societal needs is essential for an ethical approach to personal data, but there is an asymmetry whereby an excessive emphasis on an individualistic approach may be easily rectified with the consensus of the individuals, whereas a purely societal approach remains unethical insofar as it overrides too easily individual rights and cannot be rectified easily.

Societal welfare may end up justifying the sacrifice of individual rights as a means. This remains unethical. However, how this is perceived within China remains a more open question. One needs to recall that China has very poor primary care provision (Wu and Mao 2017), that it achieved 95% health coverage (via a national insurance scheme) only in 2015 (Zhang et al. 2018), it has approximately 1.8 doctors per 1000 citizens compared to the OECD average of 3.4 (Liao 2019), and is founded on Confucian values that promote group-level equality. It is within this context that the ethical principle of the 'duty of easy rescue' may be interpreted more insightfully. This principle prescribes that, if an action can benefit others and poses little threat to the individual, then the ethical option is to complete the action (Mann et al. 2016). In this case, from a Chinese perspective, one may argue that sharing of the healthcare data may pose little immediate threat to the individual, especially as Article 6 of the Regulations on the Management of Medical Records of Medical Institutions, Article 8 of the Management Regulations on Application of Electronic Medical Records, Article 6 of the Measures for the Management of Health Information, the Cybersecurity Law of the People's Republic of China, and the new Personal Information Security Specification all provide specific and detailed instructions to ensure data security and confidentiality (Wang 2019). However, it could potentially deliver significant benefit to the wider population.

The previous 'interpretation from within' does not imply that China's approach to the use of AI in healthcare is acceptable or raises no ethical concerns. The opposite is actually true. In particular, the Chinese approach is undermined by at least three main risks.

First, there is a risk of creating a market for human care. China's two-tiered medical system provides state-insured care for all, and the option for individuals to pay privately for quicker or higher quality treatment. This is in keeping with Confucian thought, which encourages the use of private resources to benefit oneself and one's family (Wu and Mao 2017). With the introduction of Ping An [sic] Good Doctor's unmanned '1-min clinics' across China (of which there are now as many as 1,000 in place), patients can walk in, provide symptoms and medical history, and receive an automated diagnosis and treatment plans (which are only followed up by human clinical advice for new customers), it is entirely possible to foresee a scenario in which only those who are able to pay will be able to access human clinicians. In a field where emotional care, and involvement in decision making, are often as important as the logical deduction of a 'diagnosis,' this could have a significantly negative impact on the level and quality of care accessed across the population and on the integrity of the self (Andorno 2004; Pasquale 2015),[14] at least for those who are unable to afford human care.

Second, in the context of a population that is still rapidly expanding yet also ageing, China is investing significantly in the social informatisation of healthcare and has, since at least 2015, been linking emotional and behavioural data extrapolated from social media and daily healthcare data (generated from ingestibles, implantables, wearables, carebots, and Internet of Things devices) to Electronic Health Records (Li et al. 2019a, b), with the goal of enabling community care of the elderly. This further adds to China's culture of state-run, mass-surveillance and, in the age of the Social Credit System, suggests that the same technologies designed to enable people to remain independent in the community as they age may one day be used as a means of social control (The Medical Futurist 2019), to reduce the incidence of 'social diseases'—such as obesity and type II diabetes

[14] Note that the emphasis on individual wellbeing must also be contextualised culturally.

(Hawkins 2019)—under the guise of 'improving peoples lives' through the use of AI to improve the governance of social services (as stated in the AIDP).

The third ethical risk is associated with CRISPR gene modification and AI. CRISPR is a controversial gene modification technique that can be used to alter the presentation of genes in living organisms, for example for the purpose of curing or preventing genetic diseases. It is closely related to AI, as Machine Learning techniques can be used to identify which gene or genes need to be altered with the CRISPR method. The controversies, and potential significant ethical issues, associated with research in this area are related to the fact that it is not always possible to tell where the line is between unmet clinical need and human enhancement or genetic control (Cohen 2019). This became clear when, in November 2018, biophysics researcher He Jiankui revealed that he had successfully genetically modified babies using the CRISPR method to limit their chances of ever contracting HIV (Cohen 2019). The announcement was met by international outcry and He's experiment was condemned by the Chinese government at the time (Belluz 2019). However, the drive to be seen as a world leader in medical care (Cheng 2018), combined with the promise gene editing offers for the treatment of diseases, suggest that a different response may be possible in the future (Cyranoski 2019; "China opens a Pandora's Box", 2018). Such a change in government policy is especially likely as global competition in this field heats up. The US has announced that it is enrolling patients in a trial to cure an inherited form of blindness (Marchione 2019); and the UK has launched the Accelerating Detection of Disease challenge to create a five-million patient cohort whose data will be used to develop new AI approaches to early diagnosis and biomarker discovery (UK Research and Innovation 2019). These announcements create strong incentives for researchers in China to push regulatory boundaries to achieve quick successes (Tatlow 2015; Lei et al. 2019). China has filed the largest number of patents for gene-editing on animals in the world (Martin-Laffon et al. 2019). Close monitoring will be essential if further ethical misdemeanours are to be avoided.

5 Conclusion

In this article, we analysed the nature of AI policy within China and the context within which it has emerged, by mapping the major national-level policy initiatives that express the intention to utilise AI. We identified three areas of particular relevance: international competitiveness, economic growth, and social governance (construction). The development and deployment of AI in each of these areas have implications for China and for the international community. For example, although the 'trump-card' policy to gain a military advantage may not be something new, its application to AI technologies risks igniting an arms race and undermining international stability (Taddeo and Floridi 2018). Efforts to counteract this trend seem largely hollow. Our analysis indicates that China has some of the greatest opportunities for economic benefit in areas like automation and that the country is pushing forward in AI-related areas substantially. Nonetheless, efforts to cushion the disruptions that emerge from using AI in the industry are currently lacking. Thus, AI can help foster increased productivity and high levels of growth, but its use is likely to intensify the inequalities present within society and even decrease support for the government and its policies. The AIDP also promotes AI as a way to help deal with some of the major social problems, ranging from pollution to standards of living. However, positive impact in this area seem to come with increased control over individuals' behaviour, with governance extending into the realm of moral behaviour and further erosion of privacy.

Ethics also plays a central role in the Chinese policy effort on AI. The AIDP outlines a clear intention to define ethical norms and standards, yet efforts to do so are at a fledgling stage, being broadly limited to high-level principles, lacking implementation. Analyses of existing Chinese approaches and emerging debates in the areas of privacy and medical ethics provide an insight into the types of frameworks that may emerge. With respect to privacy, on the surface, recently introduced protections may seem robust, with definitions of sensitive personal information even broader than that used within the GDPR. However, a closer look exposes the many loopholes and exceptions that enable the government (and companies implicitly endorsed by the government) to bypass privacy protection and fundamental issues concerning lack of accountability and government's unrestrained decisional power about mass-surveillance.

In the same vein, when focusing on medical ethics, it is clear that, although China may agree with the West on the bioethical principles, its focus on the health of the population, in contrast to the West's focus on the health of the individual, may easily lead to unethical outcomes (the sacrifice imposed on one for the benefit of many) and is creating a number of risks, as AI encroaches on the medical space. These are likely to evolve over time, but the risks of unequal care between those who can afford a human clinician and those who cannot, control of social diseases, and of unethical medical research are currently the most significant.

China is a central actor in the international debate on the development and governance of AI. It is important to understand China's internal needs, ambitions in the international arena, and ethical concerns, all of which are shaping the development of China's AI policies. It is also important to understand all this not just externally, from a Western perspective, but also internally, from a Chinese perspective. However, some ethical safeguards, constraints and desiderata

are universal and are universally accepted and cherished, such as the nature and scope of human rights.[15] They enable one to evaluate, after having understood, China's approach to the development of AI. This is why in this article we have sought to contribute to a more comprehensive and nuanced analysis of the structural, cultural and political factors that ground China's stance on AI, as well as an indication of its possible trajectory, while also highlighting where ethical problems remain, arise, or are likely to be exacerbated. They should be addressed as early as it is contextually possible.

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