Diagnostic testing of oral fluid (oral tran-
sudate or saliva) is becoming more wide-
spread, with the result that more data
are becoming available at the point of care.1,2
The applications of oral-fluid testing include
but are not limited to the identification of
patient-specific salivary oligosaccharides that
can be used to assess susceptibility to caries
before the onset of disease;3 the discovery of
genomic targets, such as salivary transcrip-
tome, which may have discriminating power
in the detection of oral cancer;4 microfluidic
immunoassay of matrix metalloproteinase-8
to assess periodontal disease;5 rapid detection
of antibodies to HIV-1 and HIV-2;6 determina-
tion of oncogene protein byproducts in pa-
tients with breast cancer;7 and measurement
of C-reactive protein, a biomarker for poten-
tial cardiac events (e.g., myocardial infarc-
tion).8 In particular, routine testing for HIV in
dental practice and prompt referral of patients
to physicians for confirmation of preliminary
test results would promote public health.9
In addition to such public health benefits,
these biotechnological advances in oral-fluid
testing could bring together dental and health
care professionals to ensure a continuum of
patient care.

Commercial Developments
The biotechnology industry has under-
taken a major financial enterprise in saliva,
and a wantonly expectorated fluid has now
become a form of capital. The biotechnology

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**ABSTRACT**

Major advances in the testing of oral fluid (e.g., saliva) may lead to the diagnosis and
treatment of previously undiagnosed conditions and may enable dentists to manage oral
disease more effectively. Such use of another body fluid, blood, is already well estab-
lished. Blood is a complex tissue that has been extensively researched and is now used for
a wide variety of diagnostic tests. It is also regarded as a form of property with ethical
and legal dimensions. If saliva is to fulfill a similar role, it should perhaps be granted
those same protections. This paper advances the concept that saliva should be consid-
ered a form of property, possibly within personal biological materials law. The emerging
potential for the development of marketable products from oral fluids raises the issue
of protecting the research participant’s ethical and legal rights. In particular, violation of
privacy and genetic discrimination may arise from the testing of salivary DNA. Respect
for autonomy requires that the clinician inform a patient or research participant about
his or her rights to property and privacy as these may pertain to oral fluid.

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company 23andMe (Mountain View, CA), as well as a number of other “personal genome” companies, now offer commercial decoding of DNA obtained from saliva to assess a person’s genetic risk for a wide range of diseases, including colorectal cancer, heart disease, breast cancer and obesity. The company provides a convenient “spit kit” to facilitate specification of the individual’s genome. A second company, Navigenics (Redwood Shores, CA), also has developed a robust financial resource in saliva by creating a “genetic health compass” to guide consumers toward optimal health. This tool matches the person’s genes to current medical research and assesses his or her genetic risk for a range of diseases. These companies have ushered in the era of retail genomics, hoping to empower individuals to access and understand their own genetic information. By providing saliva in a vial, their customers are becoming early adopters of personalized medicine, with therapy tailored to individual diagnosis.

Clarke and colleagues discussed how the integration of technoscientific innovations, such as oral-fluid testing, has coalesced into what they call biomedicalization, a second major transformation of modern American medicine (the first being the institutionalization of medicine by the end of the Second World War). Biomedicalization is a paradigm of definition, diagnosis (through screening and testing), treatment of risks, and commodification of health and lifestyles. These may be welcome advances in health care, but the potential for misuse of genetic information may loom even larger with more advances in oral-fluid testing. What ethical issues does this brave new world raise for dentists?

**The Paradigm of Property**

Blood is a complex biological tissue that is extensively tested for both medical and legal purposes. In some jurisdictions, blood is also regarded as a form of property, with certain legal protections, and it is the subject of legal and ethical reflection that is both complex and substantial. Blood is considered a tissue because it consists of groups of cells that perform certain functions. In contrast, a body part, such as a kidney, is composed of more than one tissue but is also regarded as a form of property. Oral fluid is neither a tissue nor a body part and therefore cannot be deemed a biological property analogous to blood (a tissue) or a kidney (a body part). However, that does not necessarily mean that saliva does not merit certain protections. Even though oral fluid is not analogous in its makeup to a tissue or a solid organ, it can provide analogous types of information about individuals that courts and general public opinion deem worthy of protection. Therefore, the same kinds of questions that are raised vis-à-vis tissues and body parts can also be raised vis-à-vis body fluids such as saliva. For example, should a patient have the right to control what will be done to his or her oral fluid and to receive financial compensation when it is put to research, diagnostic or therapeutic uses, as is the case for blood, other tissues and body parts? If an investigator interested in developing products from these fluids ensures that the research participant is adequately informed about the potential for a lucrative commercial market, does that also constitute adequate protection of the participant’s legal and ethical rights? Similarly, is failure to adequately inform a research participant about a potential market for his or her oral fluid sample considered a violation of the person’s property rights? In exactly what specific contexts might such decisions be made? We argue here that even though body fluids such as saliva are not exactly analogous to blood, these urgent questions compel us to regard and protect saliva as a form of personal property.

Arguing that tangible items are generally considered to be property, Andrews raised the question of whether new, potentially marketable products or uses derived from blood or body parts that unfold in the course of research, diagnosis and therapy should also be considered property. As an example, Andrews discussed the case of John Moore, a patient with leukemia, who in 1984 underwent splenectomy at the University of California, Los Angeles School of Medicine. Moore claimed that, without his knowledge or explicit consent, his physicians had used his blood to develop the patented and commercially valuable Mo, a human T lymphoblastic cell line. In 1990, the Supreme Court of California ruled in the Moore case that although patients do not have property rights over tissue removed from their bodies during medical treatment, they do have a right to decide how that material will be used in the future. The Moore case set the precedent for many subsequent rulings in personal biological materials law.

In another landmark case, Hideaki Hagiwara, a postdoctoral student in biology at the University of California, San Diego, suggested to his faculty mentor that a human monoclonal antibody be made with cancer cells from Hagiwara’s mother. Once the modified cell line had been created in the laboratory, Hagiwara felt that his family had an economic interest, because he had proposed the project and his mother had provided the original cells. A settlement in the case was ultimately reached, which gave the University of California the patent and the Hagiwaras an exclusive licence for the cell line in Japan and Asia. These 2 legal cases underscore
the tenet that a patient retains certain rights related to the use of a body part or fluid tissue, like blood, even after that part is separated from the patient’s body. Much more jurisprudence, legislation and legal theory are available in the area of property rights for human cells and tissues, but a full discussion of this legal domain is beyond the scope of this paper. Nonetheless, these 2 examples suggest that the legal and ethical ramifications extend to a patient’s potential share in the profits derived from the application of research from his or her oral fluid.

The issue may be complex even in the case of a seemingly worthless bodily byproduct like saliva. For example, a research participant may regard a bodily excretion such as urine (or perhaps saliva) as valueless, which might prompt research investigators to ask why financial compensation is even necessary. After all, individuals are generally not hesitant to freely part with large amounts of these fluids on a daily basis. However, the lack of financial compensation to a research participant for a body part or body fluid that is typically discarded in everyday life should not determine the person’s ethical and legal rights. Advances in biotechnology have shown that a previously “valueless” body fluid can represent a lucrative commodity, and biotechnological companies like 23andMe and Navigenics now have a profitable commercial market in seemingly “valueless” body fluids like saliva.

The Paradigm of Privacy

Tabak has argued that, given the DNA content of saliva and hence the potential for genetic discrimination and violation of privacy, this body fluid should be viewed no differently from a blood sample. However, concerns about privacy do not necessarily lead to a property paradigm, as outlined in the previous section. The right to privacy of personal genetic information and safeguards against unwarranted disclosure or manipulation of that information can in fact be separated from the proposed status of saliva as a biological property and its attendant rights.

Before the genomic era, the storage of human tissues in a pathology laboratory was generally without consequence, because personal genetic information could not be obtained from them. Be that as it may, the public still worried about how information about their genetic makeup might be used in harmful ways, and policymakers began considering legislation to prevent misuses of genetic information. As genetic science advanced, human tissues, including blood, and body fluids, like saliva, came to be recognized as storehouses of information about their respective donors. Obtaining this genetic information has been greatly facilitated through advances in modern biotechnology, and marketing and testing of blood and saliva are now widely available. As a result, there is an increased risk of genetic discrimination, which occurs when a person is treated differently by an insurance company or employer because of a gene alteration that increases the risk of a disease such as cancer.

Who protects patients’ genetic privacy? More than 25 years ago, Siegler commented prophetically that confidentiality in medicine was a “decrepit concept.” That view has since been substantiated by advances in the field of information technology, through which storage systems containing personal information and the retrieval systems required to access those data have become increasingly complex. Perrow argued that the creation of more warnings and safeguards ultimately fails in its intended purpose because the complexity of the resulting systems makes failure inevitable. Breaches of confidentiality are thus typical of high-risk technologies, rendering the protection of genetic privacy a much greater challenge. Meeting that challenge will require a much better understanding of why breaches of confidentiality occur and why it is virtually impossible to prevent them. Such an understanding should lead to a better position from which to argue that certain technologies should be abandoned and that others, such as computer-based medical records systems (which cannot be abandoned because of their fundamental role in current society), should be modified.

The Principle of Autonomy

Autonomy is an overarching principle that encompasses both the property and privacy paradigms. The principle of autonomy may be generally represented by the duty or obligation to show due respect for persons. Respect for a person’s autonomy requires that clinicians inform patients or research participants of their rights to property and privacy regarding any body part, including oral fluid.
right. The right to privacy is thus justified by the right of autonomous choice that correlates with the obligations expressed in the principle of autonomy.

Conceptually, informed consent and confidentiality flow from this basic principle of autonomy. Breaches of confidentiality and privacy are thus viewed as violations of personal autonomy. One important purpose of the doctrinal principle of informed consent is to protect people from not only unnecessary treatment but also all forms of unwanted treatments, even if they are deemed medically necessary. Similarly, truly informed and voluntary consent is aimed at protecting a research participant not only from a scientist or clinician whose motives are unscientific, but also from any unwanted participation in legitimate research projects. Respect for autonomy encompasses adequate informed consent to ensure that provision of any sample (such as blood, other tissue or saliva) for investigative purposes is done voluntarily with the full understanding of its potential uses and safeguards to protect against unwarranted disclosure of confidential information. Respect for autonomy also obligates a clinician who plans to use tissues or fluids for research purposes to fully inform the patient or research participant of those plans. In addition, respect for autonomy includes a fundamental obligation to ensure that patients or research participants have the right to choose freely. Forced choice and evasive disclosure are inconsistent with this obligation.

Some have argued that autonomy has become the primary ethical principle in modern health care. Although that level of emphasis upon autonomy is recent, especially in the ethics of health care, its roots, which focus upon individuals’ free choice, go at least as far back as Immanuel Kant’s obligation-based theory. Rapid advances in the biotechnology industry of diagnostic testing may restrict or promote autonomy. For example, the marketing of personalized genomic medicine may capitalize on the public’s fears of terminal illness and unduly influence consumers to buy certain products. Because contemporary consumers’ choice to purchase items such as “spit kits” is based on fear, and not necessarily on a rational analysis of the true usefulness of the product, some would argue that such a decision is not truly autonomous. Respect for autonomy requires that proper counselling by trained health care professionals be provided in advance to enable consumers to make their own informed health care decisions and to help them understand that a predicted genetic risk, for example, does not necessarily mean that they will actually get the disease. Ultimately, then, personalized genomic medicine may promote autonomy and empower individuals to access and understand their own genetic information, but misinterpretation of genetic information is likely unless consumers receive proper counselling.

Conclusion

Oral-fluid testing and mechanisms for prompt referral of patients to physicians may lead to the diagnosis and treatment of previously undiagnosed conditions, as well as enabling dentists to monitor and manage the course of oral disease more effectively. Such testing has also become a potentially valuable aspect of research in the current genomic age. However, such welcome advances in the biotechnology of oral-fluid testing raise ethical and legal ramifications regarding the status of saliva as a biological fluid.

Like blood, saliva is associated with property and privacy paradigms and their associated quandaries. If a marketable product is developed from saliva, then the paradigm of property rights emerges because of the potential for financial compensation. Failure to adequately inform a person of that potential may therefore represent a violation of that person’s property rights. In addition, the violation of privacy related to the unwarranted disclosure of genetic information obtained through oral-fluid testing poses a significant quandary. Saliva represents a major genetic database, like blood. In the modern era of information technology, oral-fluid testing creates a Pandora’s box, with attendant threats of accidental release and potential misuse of genetic information. Highly complex storage and retrieval systems inevitably fail in one way or another, and violation of privacy is therefore common. Paradoxically, introducing more safeguards tends to make such systems less secure, thereby increasing the challenge to protect privacy. Respect for autonomy requires that dentists inform patients of their rights to property and privacy regarding their own oral fluids. Such a requirement may eventually reshape the provision of dental care.

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