Patient autonomy within real or valid consent: Samira Kohli's case

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Abstract

In bioethics literature, the primary justification for the requirement of informed consent has been the protection of autonomous choices. To allow patients to be autonomous decision-makers, physicians are supposed to disclose and share information related to all treatment, procedures and risks. Advocates of the autonomy-based informed consent model argue that in informed consent cases, the disclosure of information should be according to the reasonable person standard or reasonable patient standard, rather than the average competent physician standard. In the Indian medico-legal context, the concept of consent has evolved through the discussion of informed consent and by referring to the concepts of informed consent in other countries, such as the USA, the UK and Canada. In cases of medical negligence in India, the concept of "real or valid consent" has been adopted from British case law rather than the "informed consent" of the USA. This paper examines the doctrinal rules of the concept of real or valid consent through an analysis of Samira Kohli's case – a landmark court case and a major precedent case in India that referred to "real or valid consent". In analysing this case, the paper will examine the judiciary's decision on the nature of and standard for the disclosure of information. Thus, the paper will reflect on the underlying ethical and legal principles of the doctrine of real or valid consent in the Indian context. This paper uses a hermeneutic approach to the landmark case to provide a qualitative interpretation of the Indian medical judiciary's concept of consent and the autonomy of the patient.

Introduction

The intertwining nature of law and ethics is evident as both focus on right and wrong behaviours of human beings. Though they intertwine, they differ in their ability to enforce ethical behaviour. We can identify and reflect on society's moral views and morality by looking at the law of the land. Thus legal resolution becomes a societal consensus statement on ethics (1). One of the issues that comes up in medicine and law in the context of the doctor–patient relationship is "informed consent". This issue, which was adopted from clinical ethics, has been at the forefront of biomedical ethics since the Nuremberg trials and other instances of experimentation with human beings (2). The proponents of "informed consent" have mooted the idea in various forms – from shared decision-making to an autonomous authorisation by individuals about to undergo medical interventions or participate in research (3).

The development of informed consent is well documented, both in tort law and common law jurisdictions, and is directly linked with an individual's self-determination (4). Self-determination is primarily the right to non-interference, where an individual has the right to make decisions concerning one's own life without the control or interference of others (5). The doctrine of informed consent can be traced to American law and the emphasis has been on individual autonomy(6). As a legal doctrine, it was first formulated in the case of Canterbury vs Spence, 1971 (7) in the USA. This case involved a boy who suffered paralysis after back surgery. He claimed he was not informed adequately about the risks involved in the surgery. The court argued against the physician's standard of disclosure of information and held the patient's standard of informed consent reasonable. The Canterbury Court held that the standard of disclosure of information should take the individual circumstances of a patient into consideration. Thus, this case emphasised the patient's autonomy, which demands that the physician provide information to the patient as a duty. While in the UK, informed consent was recognised initially in Sidaway vs Board of Governors of the Bethlem Royal Hospital and the Maudsley Hospital and others, 1985 (8), it was not recognised exactly in the sense in which it is applied in the USA. In this case, the operation performed by the surgeon left the patient paralysed. The plaintiff alleged that the surgeon was negligent as he failed to disclose or explain the risks inherent in the operation. The judge applied the "Bolam test", which was first laid down in Bolam vs Friern Hospital Management Committee, 1957 (9). Under the Bolam test, professional standards were set according to peer standards of professional conduct. This means that it is doctors who decide how much to tell patients about the risks of treatment and, therefore, a doctor cannot be sued if he/she fails to inform the patient about the risks if other reasonable doctors would not have informed the patient about them in the given situation.

To understand the concept of "real or valid consent" and its ethical and legal underpinning in cases of medical negligence in Indian courts, this paper will analyse the landmark case, Samira Kohli vs Dr Prabha Manchanda, 2008 (12). It is important to analyse this case because it is a precedent case which has set forth the nature of real or valid consent and has discussed the standard of the disclosure of information. Also, this case has been referred to till recently (recent case, Vimhans Hospital and Ors. vs Anand Kumar Jha and Ors, 2015) (13). Though the

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Samira Kohli (12) case has been discussed and referred to in bioethical literature, it has not been critically analysed to understand the concept of real or valid consent. Apart from attempting such an analysis, this paper will also reflect on the patient's autonomy, as it has been a central theme in the discussion on "informed" consent.

In the next section, I shall outline the relationship between informed consent and the principle of patient autonomy. This is followed by a discussion of the existing legal principles under which real or valid consent is protected. I then go on to examine the underlying ethical and legal principles of real or valid consent, with the help of an analysis of the Samira Kohli (12) case. In the ensuing section, I present the nature of the standard of disclosure of information discussed in the case and critically examine its ethical basis. There follows a discussion of the judiciary's priority in cases of medical negligence and the justification. I conclude the paper with my critique of the judiciary's present viewpoint.

Patient autonomy and informed consent – through the legal lens

The language of human rights in the 21st century, which seeks to redress power imbalances, recognises and gives importance to individual rights in all areas of human life. The concept of self-determination, which evolved from liberal thought, plays a very important role in the contemporary doctor–patient relationship (14). The growth of scientific and medical knowledge, advances in medical technology, differences in expert advice and medical uncertainties strengthen the case for decision-making by the person, ie "patient", whose life is directly involved. Thus, the patient's autonomy has become a central principle both of the popular and philosophical analysis of medical decision-making (15). Informed consent, which emanates from the principle of autonomy, is an outcome driven by the culture of consumerism, intertwined with human rights and liberal values, in American society (16,17). It refers to the duty of physicians, before they treat a patient, to explain the procedure to the patient and warn them of any material risks or dangers inherent in or collateral to the procedure, so as to enable the patient to make an intelligent and informed choice about whether to undergo treatment within clinical practice (17). The primary function and justification of informed consent is to enable an individual to make an autonomous choice and protect his or her choice (1). The ethical imperative to respect the patient's autonomy has shifted the focus of authority in medical decision-making from the physician to the patient. Moral principles are enforced by the law in the form of rights and duties (18).

Judges and legal scholars have long asserted the importance of patient autonomy or self-determination in medical decision-making. The locus classicus remains the judgment of Cardozo J. in Schloendorff vs Society of New York Hospital, 1914 (16).

> *Every person being of adult years and sound mind has a right to determine what shall be done with his own body*.

Autonomy has been recognised as a legally protectable interest and has been vindicated as a byproduct of protection for two interests – bodily security, as protected by rules against unconsented physical contact, and bodily well-being, as protected by rules governing professional competence (14). These interests, in short, can be termed as bodily integrity and individual self-determination, which reflect the principle of patient autonomy. The right to bodily integrity is embodied in common law through civil and criminal laws on assault and battery (20). There are also constitutional underpinnings to this right, and to the right to individual self-determination. Informed consent has evolved through lawsuits and this concept will be evolving, as jurisprudence grows under common law. We can trace the transition from simple, voluntary to informed consent. In Slater vs Baker and Stapleton (21) in 1767, the surgeon had to obtain consent from the patient before beginning the treatment; and in Schloendorff vs Society of New York Hospital (19) in 1914, voluntary consent was emphasised, ie the patient had to give permission for a specific procedure. In the Salgo vs Leland Stanford Junior University Board of Trustees (22) case (1957), it was held that physicians had an affirmative duty to disclose information. By referring to the above cases, we can see how the doctrine of informed consent has evolved over a period of time.

According to the present understanding of the doctrine of informed consent, patients have to be fully informed by practitioners about the risks, benefits and other aspects of the treatment, and must also be given information on the option of receiving no treatment. The widely accepted building blocks of the concept of informed consent are competence, disclosure, understanding, voluntariness and consent (3), which are based on the autonomy model. In the cases mentioned above and lawsuits, the central focus has shifted from consent to treatment to the physician's duty to disclose information. Thus, the element of disclosure of information has gained importance in cases involving consent. It is important to understand which existing legal protection safeguards the patient's autonomy to analyse the legal and ethical source of the concept of consent. Here, when I refer to existing legal protection, it means whether it is under the battery or professional negligence theory.

Samira Kohli's case – an analysis

In India, laws governing medical negligence are derived from English common law. An individual who has been affected by medical negligence or malpractice can approach the judicial system under the Civil Procedure Code, Criminal Procedure Code (S 304 A, Indian Penal Code), Consumer Protection Act (CPA), 1986 (23), and Code of Medical Ethics Regulations, 2002 for disciplinary action (24). Jurisprudentially, there is no distinction between negligence under the civil code and the criminal code. It is the amount of damages incurred which determines the extent of liability in tort; in the criminal code/law, it is not the damages but the degree of negligence (25). A person who seeks financial compensation files a case against medical professionals under the CPA since it is the easiest way to have one's grievance redressed and receive compensation

(26, 27). To clarify the concept of real or valid consent in Indian medical law, I will first outline the facts of the Samira Kohli case (12), as this was the first case which explicitly discussed real or valid consent to treatment.

Outline of case facts

Samira Kohli, an unmarried woman, aged 44 years, consulted Dr Manchanda on May 9, 1995, complaining of prolonged menstrual bleeding. She was admitted and the consent form for hospital admission, medical treatment and also, surgery, were signed. The consent form for surgery said "diagnostic and operative laparoscopy. Laparotomy may be needed". She was subjected to a laparoscopic examination under general anaesthesia. While Samira was unconscious and was being examined, Dr Lata Rangan came out of the operation theatre and took the consent of the patient's mother for a hysterectomy. After her mother's consent was obtained, Dr Manchanda removed the patient's uterus (abdominal hysterectomy), ovaries and fallopian tubes (bilateral salpingo-oophorectomy). On January 19, 1996, Samira Kohli filed a complaint before the National Consumer Disputes Redressal Commission, claiming compensation of Rs 25 lakh from Dr Manchanda. She complained that the doctor had been negligent and that the radical surgery, by which her uterus, ovaries and fallopian tubes had been removed, had been performed without her consent. The compensation claimed was for the loss of her reproductive organs, diminished prospects of matrimony, irreversible damage to the body, loss of the opportunity to become a mother, as well as painful emotional trauma. The National Commission dismissed the complaint, declaring that the hysterectomy had been performed with adequate care and also, that the patient had voluntarily sought treatment at the clinic. A plea was filed at the apex court. Overruling the order passed by the National Consumer Dispute Redressal Commission, the Supreme Court held the doctor liable for malpractice. The Supreme Court opined that while additional surgery was beneficial to the patient in terms of saving time, suffering, pain and expenses, this was no ground for defence. It provided further details regarding consent and the disclosure of information.

The *ratio decidendi*, ie the rationale for the decision in this judgment, was rooted in assault and battery. The physician performed an unauthorised abdominal hysterectomy–bilateral salpingo-oophorectomy (AH-BSO), without obtaining the specific consent of the patient. Though the physician received consent from the patient's mother, it is not considered valid since it amounts to trespass of the bodily integrity of the patient and deficiency in service (12). In law, the right to self-determination and fiduciary duty protect patients from unwarranted intrusions, such as surgery without consent, by physicians (18). Though the judges initially invoked the battery theory to discuss the breach of duty, the case was later considered under the negligence theory of liability, under which compensation is provided to the plaintiff. Thus, we can see the shift in the concept of consent in medical cases from one centred around battery to one focusing on the negligence theory. According to the latter theory, unintentional or careless action itself is the source of liability (18). This means that a surgery performed without consent is an act of negligence and thus, the physician is guilty. In this case, the judgment not only provided details regarding specific consent to additional surgery, but elaborated on the meaning of consent and the nature of the disclosure of information. It also set guidelines to be adopted in the Indian context by referring to cases decided by British courts. Understanding the meaning of consent and the standard of the disclosure of information helps to examine the role of and importance given to the physician and the patient. It also helps to evaluate the degree of respect for the patient's autonomy, and reflects the judicial position as regards material information and central authority within the doctor–patient relationship.

Real or valid consent - what is it?

The nature of express consent differs in the UK and the USA, being "real consent" in the former and "informed consent" in the latter. In the Samira Kohli case, the judge referred to both meanings of consent and then decided that the UK definition should be followed in the Indian context. The judgment consciously preferred the "real consent" concept evolved in Bolam (9) and Sidaway (8) over the "informed consent" concept in Canterbury (7), referring to the ground realities of medical care and healthcare in India. Below is an excerpt from the Samira Kohli case judgment that discusses real consent and informed consent.

> *There is, however, a significant difference in the nature of express consent of the patient, known as 'real consent' in the UK and as 'informed consent' in America. In the UK, the elements of consent are defined with reference to the patient and a consent is considered to be valid and 'real' when (i) the patient gives it voluntarily without any coercion; (ii) the patient has the capacity and competence to give consent; and (iii) the patient has the minimum of adequate level of information about the nature of the procedure to which he is consenting to. On the other hand, the concept of 'informed consent' developed by American courts, while retaining the basic requirements of consent, shifts the emphasis to the doctor's duty to disclose the necessary information to the patient to secure his consent*... (12: p 6).

Thus, the USA emphasises the "duty" of the physician to disclose information to the patients. In the Canterbury case, the central focus was on the disclosure of information on risk. Patients were considered as the sole authorities who know their own circumstances best, and physicians were seen as being responsible for providing the information available and communicating it to the patients for them to make the decision. All the potential risks which may affect the decision should be shared with patients. In this US case, the physician's obligation or duty was to fulfil the patient's need for the information material to the decision. Here, the patient's right of self-decision shapes the boundaries of the duty to reveal (5).

In the Bolam (9) and Sidaway (8) cases in the UK, the concept of consent was determined by the standards of medical professionals. The central discussion in the Bolam case referred to the medical standards regarding the use of relaxant drugs. It was decided that the doctor was not negligent if he had practised in accordance with the practice accepted by a responsible body of medical professionals, and was negligent if he had done otherwise. In the Sidaway case, a patient was left paralysed after an operation to relieve a trapped nerve. The physician had not informed the patient of the risks involved in the treatment. Here, the case discussion was on the disclosure of risk. The judge applied the Bolam Test (discussed earlier), and rejected the appellant's claim that a respectable body of medical opinion agreed that it was not necessary to warn a patient of every risk. Though the appeal was rejected, the case established that "a doctor has a duty to provide to their patients sufficient information for them to reach a balanced judgment" (8).

As for the Samira Kohli case, the following excerpts from the judgment throw some light on the nature of the standard of disclosure of information.

> *As in judgment, the consent so obtained should be real and valid, which means that: the patient should have the capacity and competence to consent; his consent should be voluntary; and his consent should be on the basis of adequate information concerning the nature of the treatment procedure, so that he knows what he is consenting to.* (12: p 15)

Here, we can question how "adequate information" should be defined and what information counts as "adequate" in the case of a particular patient. The excerpt below explores this.

> *…The 'adequate information' to be furnished by the doctor (or a member of his team) who treats the patient, should enable the patient to make a balanced judgment as to whether he should submit himself to the particular treatment or not. This means that the doctor should disclose (a) the nature and procedure of the treatment and its purpose, benefits and effect; (b) the alternatives, if any available; (c) an outline of the substantial risks; and (d) the adverse consequences of refusing treatment. But there is no need to explain the remote or theoretical risks involved, which may frighten or confuse a patient and result in refusal of consent for the necessary treatment. Similarly, there is no need to explain the remote or theoretical risks of refusal to take treatment which may persuade a patient to undergo a fanciful or unnecessary treatment. A balance should be achieved between the need for disclosing necessary and adequate information and at the same time avoid the possibility of the patient being deterred from agreeing to a necessary treatment or offering to undergo an unnecessary treatment…* (12: p 15).
>
> *(v) The nature and extent of information to be furnished by the doctor to the patient to secure the consent need not be of the stringent and high degree mentioned in Canterbury but should be of the extent which is accepted as normal and proper by a body of medical men skilled and experienced in the particular field. It will depend upon the physical and mental condition of the patient, the nature of treatment, and the risk and consequences attached to the treatment*. (12: p 16).

These excerpts give us a fair idea of the nature of the standards of disclosure of information. Though the disclosure of adequate information is discussed and the importance of the physician giving balanced information is stressed, the judgment does not discuss the need to give the patient material information. Also, in this judgment, respect for the patient's autonomy is not protected by the application of the Bolam test to consent cases. As we analyse the matter deeper along these lines, we see that the moral responsibility for disclosing information and the amount or kind of information disclosed rests with physicians, after they have considered the circumstances. Though it appears considerate enough that the physician should contemplate the practical situation and other factors, this reaffirms that the physician has the power to disclose or withhold information, and does not highlight the importance of giving the patient material information. Thus, the judgment gives importance to physician-oriented standards rather than material information for the patient.

The following excerpt from the judgment provides the rationale behind applying the Bolam principle in the Indian context, and makes us question its deeper relevance to the protection of the patient's autonomy. In fact, this would also help us answer the question of how to deal with patient autonomy in the present context.

> *…There is a need to keep the cost of treatment within affordable limits. Bringing in the American concepts and standards of treatment procedures and disclosure of risks, consequences and choices will inevitably bring in the higher cost structure of American medical care. Patients in India cannot afford them. People in India still have great regard and respect for doctors. The members of the medical profession have also, by and large, shown care and concern for the patients. There is an atmosphere of trust and implicit faith in the advice given by the doctor. The Indian psyche rarely questions or challenges medical advice. Having regard to the conditions obtaining in India, as also the settled and recognised practices of the medical fraternity in India, we are of the view that to nurture the doctor–patient relationship on the basis of trust, the extent and nature of information required to be given by doctors should continue to be governed by the Bolam test rather than the 'reasonably prudential patient' test evolved in Canterbury (7). It is for the doctor to decide, with reference to the condition of the patient, the nature of the illness, and the prevailing established practices, how much information regarding the risks and consequences should be given to the patient, and how it should be couched, having the best interests of the patient... (12: p 15)*.

Thus, when we examine Samira Kohli's case, we can pose some major questions, such as the following. What is the legal and

ethical approach to the patient's right to information? What does it mean when judges say that the UK's Bolam test should be applied in the Indian context? How does "real consent" differ from "informed consent"? Why should we adopt "real consent" and why can we not adopt "informed consent"? How is the patient's autonomy affirmed, given that it is the physician's responsibility to disclose or withhold information? Further, how should we then see patient autonomy in the Indian context?

Revisiting patient autonomy at the ethical and legal juncture

As we have seen, the discussion in the Samira Kohli case initially centred on battery, then shifted its focus to the negligence theory of liability. Indian courts dealing with medical negligence cases that involve consent apply the professional standard of information disclosure, like the British courts before the Montgomery vs Lanarkshire Health Board, 2015 case (10). (The reasonable person standard of disclosure, as opposed to the professional standard, was applied in this case.) Indian courts do not apply the reasonable person standard or the material risk standard, which requires a physician to disclose all the information an individual needs to make an informed decision about whether to undergo a particular treatment. The reasonable person standard is based on the principle of self-determination (16). This standard was followed in Canterbury vs Spence (7). The philosophical basis for the progression from the reasonable physician standard to the reasonable person standard of information disclosure is the promotion of the ethical ideal of patients' autonomy. The professional standard of disclosure, on the other hand, reinforces physician paternalism, which impinges on the patient's autonomy (15). This approach was adopted in the UK before the Montgomery vs Lanarkshire Health Board, 2015 case. In this case, the justification provided for departing from the approach of the earlier rulings was "the doctor's duty to advise her patient of the risks of the proposed treatment falls outside the scope of the Bolam test" (10).

Under the real or valid consent doctrine, the physician's obligation to disclose information on the treatment depends on the practice accepted by the medical professional community. This is nothing but the application of the Bolam principle. The question is whether the Bolam principle can be applied to cases involving the disclosure of information, as it would mean giving priority and authority to medical professionals rather than patients. This was questioned in the Montgomery vs Lanarkshire Health Board case, which became a landmark case in the UK, reversing as it did the law on consent. The precedent cases on the law of consent before this case were Bolam vs Friern Hospital Management Committee, 1957 ("Bolam"), and Sidaway vs Board of Governors of the Bethlem Royal Hospital and the Maudsley Hospital, 1985 ("Sidaway"). In India, it remains to be seen whether in the future, we will stick to Bolam and Sidaway or apply Montgomery. In the Samira Kohli case, and also in the recent Vimhans Hospital and Ors vs Anand Kumar Jha and Ors, 2015 case, Bolam and Sidaway were followed. This makes one wonder how the patient's autonomy is protected under the real or valid consent doctrine.

In legal literature, under theories of liability, when the doctrine of informed consent is discussed, battery and negligence theory of liability are invoked (18). In the Samira Kohli case, we notice that under the battery theory of liability, the physician is held negligent under tort law. This case has paved the way for the application of the Bolam principle in deciding the standard of information disclosure, stating that "adequate information" should be provided to the patient. As discussed earlier, advocates of autonomy have argued that the standard for disclosure should be in keeping with what a reasonable patient would want to know, rather than what the average competent doctor would actually disclose (14). Doctors are trained to take active responsibility with regard to outcomes and also, historically, they have been reluctant to disclose risks and share decision-making (24, 25). The major goals of physicians and medicine are to protect individuals from harm and see to their physical well-being or overall well-being, which are protected interests. These goals are reflected in this case by giving importance to the professional standard of care.

One of the questions considered in the Samira Kohli case was "whether the respondent is guilty of the tortuous act of negligence/battery amounting to deficiency in service, and consequently liable to pay damages to the appellant". The judgment stated that it was an unwanted invasion and the physician did not obtain consent. Therefore, it amounted to battery and the respondent was guilty of "deficiency in service". The judgment also stated:

> *.....The respondent did it in the interest of the appellant. As the appellant was already 44 years old and had serious menstrual problems, the respondent thought that by surgical removal of the uterus and ovaries, she was providing permanent relief. It is also possible that the respondent thought that the appellant may approve of the additional surgical procedure when she regained consciousness and the consent of the appellant's mother gave her authority. This is a case of the respondent acting in excess of consent but in good faith and for the benefit of the appellant. Though the appellant has alleged that she had to undergo hormone therapy, no other serious repercussions arose as a result of the removal. The appellant was already fast approaching the age of menopause and in all probability, required such hormone therapy. Even assuming that the AH-BSO surgery was not immediately required, there was a reasonable certainty that she would have ultimately required the said treatment for a complete cure. On the facts and circumstances, we consider that the interests of justice would be served if the respondent is denied the entire fee charged for the surgery and in addition, directed to pay Rs 25,000 as compensation for the unauthorized AH-BSO surgery to the appellant... (12: p 23).*

This excerpt reflects that the judgment was considerate towards physicians, mentioning that the respondent acted

in the best interest of the patient. In the Samira Kohli case, consent was seen as a legal tool to establish deficiency in service and directed physicians to respect the patient's bodily integrity by stating the rationale of judgment under assault and battery. But the guidelines provided in the judgment on the disclosure of "adequate information", the decision to apply the Bolam test and the acceptance of the UK's "real consent" reflect the dominance of the professional standard of disclosure. And also the physician's duty to disclose material information to the patient was not discussed or highlighted. Here in this case the judge decided to provide compensation to the victim due to deficiency in service, which refers to physical harm to the body. Thus, this case analysis indicates that the real or valid consent doctrine has been a tool to protect the patient's bodily integrity and physical well-being. Physical well-being is considered the ultimate protected interest and not the patient's right to material information or choice. The patient's right to material information is undervalued, which reflects that the ethical principle underlying respect for the patient's autonomy is taken over or captured within the concept of patient's physical well-being.

Conclusion

In the Samira Kohli case, the Bolam test has been applied and professional standards used when considering the concept of real or valid consent and the standard of disclosure of information. When we analyse the Canterbury case and the Bolam, Sidaway and Montgomery cases, we see that the major factors differentiating the approach of each case to consent were the "risk disclosure" standard and the "duty" of the physician to disclose material information. In the Canterbury and Montgomery cases, the patient's right to information was highlighted. The professional medical standard of information disclosure was found inappropriate and the patient's choice was given importance. Medical judgments and decisions should be differentiated from patients' value judgments. Thus, physicians should be facilitators who support patients in making decisions by sharing information material to them. The autonomy of patients is respected if their choices are given importance and if the physician's "duty" to disclose information is emphasised. As for the Samira Kohli case guidelines on the standard of information disclosure, the importance of the patient's choice was evaded by giving importance to the application of the professional standard of disclosure. On the basis of this case analysis and the other court cases referred to, I feel that we cannot deny patients the right to information on socioeconomic and cultural grounds (which were mentioned in the Samira Kohli case), because the 'duty' to disclose information should be distinct from medical standards/custom and practice. For patients to exercise their choice, their right to make their own decision sets the boundary of the duty to disclose information material to them. Thus, laying emphasis on the ethical and legal principle of 'duty' to disclose material information on physicians, and applying patient disclosure standard of information protects and respects the patient's choice.

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