

Autonomy and Tuberculosis: Discussion on the Current Legislation in England

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Abstract

Tuberculosis (TB) is a major public health threat both for developing and developed countries. In the UK TB is mainly related to immigration from high TB burden regions. The prevention, care and control of Tuberculosis cannot be achieved without taking into consideration ethical aspects. This paper attempts a thorough discussion on the relationship between autonomy and some of the measures and procedures which are in force today in England regarding the control of TB. More specifically, relevant provisions of the Public Health (Control of Disease) Act 1984 -as amended- and the regulations made under this Act are going to be discussed in compliance with the WHO guidelines on ethics of TB prevention, care and control and to the Siracusa principles as formulated by the United Nations. In general, it could be claimed that the current legislation for the control of TB in England keeps a delicate balance between the right to autonomy and the need for the protection of public health. More scientific data on the necessity and effectiveness of the compulsory measures would be helpful for a consensus to be reached.

Keywords: Tuberculosis, Autonomy, Ethics, public health measures, infectious diseases

1 Introduction

Tuberculosis (TB) is a major public health threat both for developing and developed countries, related to social aspects that may affect the effectiveness of public health measures and further hinder its control [1]. Mason and Laurie in 2006[2] consider TB as the no 1 killer on a global scale. In 2010, 8.5–9.2 million TB cases were reported, leading to 1.2–1.5 million deaths globally [3,4]. One reason for a threatening come-back of TB is the increasing population infected by HIV, who are more likely to develop TB and whose mortality rate is higher [5-7]. Simultaneously, immigrant population from developing

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countries with high TB prevalence rates, the deterioration of living or working conditions as well as malnutrition, as a result of the economic crisis, are the perfect setting for the comeback of TB in countries where this risk has been underestimated [8-11]. Over the last few years, a new TB challenge has arisen; the control of the multidrug resistant form of TB (MDR-TB) and the “extensively” drug resistant TB (XDR-TB) [12].

Infectious diseases, like TB, “raise a relatively unique constellation of ethical problems”[13]. Literature on ethical and legal issues associated with infectious diseases and the protection of human rights has been growing, leading to the well established assumption that the prevention, care and control of TB cannot be achieved without taking into consideration ethical aspects, like the right to autonomy [14 – 18]. Autonomy is to be defined in the light of particular objectives, as it does not convey a single clearly defined meaning in either ordinary English or contemporary philosophy [19]. In biomedical context, autonomy is frequently considered to be the safeguard of individuals’ right “to make decisions about their own lives, including health care” [14]. In this context, the rights to dignity, self-determination, confidentiality and privacy are strongly related to autonomy. Autonomy is neither cited among the human rights principles, as adopted by the United Nations [20] nor mentioned as a term in the European Convention of Human Rights [21]. However it is suggested that it is embraced by other human rights, for example the right to liberty and security and the right to respect for private and family life, or by constitutional principles like the rule of law, accountability, non-discrimination, participation, empowerment, transparency and dignity [22]. In the United Kingdom (UK), the Human Rights Act 1998 (HRA) came into force in October 2000, consisting of a series of sections that codify the protections in the European Convention on Human Rights into UK law [23]. In England, current legislation for the control of infectious diseases like TB is mainly based on the Public Health (Control of Disease) Act 1984 [24] -as amended by the Health and Social Care Acts 2008 and 2012- and the regulations made under this Act. The Public Health Act 1984 as amended includes inter alia provisions concerning the notification of cases of infection or contamination that may pose a risk, the collection of information on a case of infection or probable infection, compulsory admission into a hospital and detention, the exclusion of infected people from several activities and the management of infected articles, premises or dead bodies. Regulations including relevant provisions are the Health Protection (Local Authority Powers) Regulations 2010, the Health Protection (Part 2A Orders) Regulations 2010 and the Health Protection (Notification) Regulations 2010. The first two determine powers and duties of local authorities and justices of the Peace in order to protect public health from the risk of significant harm due to infection or contamination, when voluntary cooperation cannot be ensured, providing “a wider and more flexible set of powers than previously existed” [3]. The former include inter alia provisions aiming to the control of infectious diseases in schools. The Health Protection (Notification) Regulations 2010 place obligations to disclosing information to specified third parties for public health reasons and provide that TB is considered a notifiable disease [25].

This paper attempts a thorough discussion on the relationship between autonomy and related rights on the one hand and some of the measures and procedures which are in force today in England regarding the control of TB, on the other. More specifically, relevant provisions of the Public Health (Control of Disease) Act 1984 -as amended by the Health and Social Care Acts 2008 and 2012- and the regulations made under this Act are going to be discussed in compliance with the WHO guidelines on ethics of TB prevention, care and control [14] and to the Siracusa principles as formulated by the United Nations in 1985 [26].

In order to examine the extent of the limitations imposed to the right of autonomy for the control of TB, we discuss the moral justification of measures like notification and detention and the relevant legislative provisions.

The provisions of both the Health Protection (Part 2A Orders) Regulations 2010 and the Health Protection (Local Authority Powers) Regulations 2010 are considered to be compatible with the Convention rights [27]. Yet, some of those who responded to the consultation of the draft versions of the aforementioned regulations were of the opinion that the rights of those who might be the subject of an order of a justice of the peace are not sufficiently protected [27]. Therefore, it is clear that there is no consensus about whether the right to autonomy is sufficiently protected in relation to the provisions regarding the protection of public health from infectious diseases.

Yet, there should be a consensus that the restrictions of such important principles such as autonomy should be the least restrictive, proportional to their goal and applied only when necessary. These pre-suppositions for the justification of restrictions were included in the Siracusa principles as formulated by the United Nations in 1985 [26]. According to these principles, restrictions of the human rights should be *“legal, neither arbitrary nor discriminatory, proportionate, necessary, the least restrictive means that are reasonably available under the circumstances, and based on sound science. Moreover, any restriction must be of a limited duration, respectful of human dignity and subject to review”* [28].

2 Notification

One of the most important public health measures for the control of TB in England is the duty of registered medical practitioners to notify the designated officer of the local authority of reasonably suspected cases of TB, or of cases of identification of the mycobacterium tuberculosis complex in human samples [24, 25]. The notification of TB is compulsory in all European countries and central registers exist in all of them [29]. The importance of this measure lies mainly in the contribution to the early detection of a possible outbreak (surveillance) [30], as it provides useful information for reviewing and updating immunisation programs, and for planning targeted or specialist health services and primary care services [27]. In the Health Protection (notification) Regulations there is not any provision that the patient should be informed about the notification, nor that their informed consent should be sought. It could be considered that both could apply in case of notification, as any “collection, reporting and storage” of personal information should be done in accordance with the Data Protection Act 1998 [31]. Yet, in case of lack of informed consent, appropriate “information can be disclosed under the statutory requirement for notification and under public interest justification” [31]. According to Rockville [32] the patient should be informed of the relevant legislation and be reassured about the appropriate use of confidential information. Gostin et al [33] state that “subjects are entitled to know the purposes for the data collection and how the information will be used, the length of time that the data will be stored and the circumstances under which it will be expunged, and the degree to which third parties (eg, regulators, researchers, and governmental officials) may obtain access”.

The above opinions comply with the WHO guidelines on the ethics of TB prevention, care and control [14], which makes a clear distinction between routine public health surveillance activities, like notification and epidemiological research. According to these guidelines, individuals should not be granted the right to refuse the disclosure of their personal

information for the purposes of public health surveillance. Therefore, asking them to provide informed consent could be considered “misleading”. Yet, it is desirable they should receive information about the notification, its content, purpose, procedures and results.

The practice of notification raises important issues in relation to the protection of privacy and confidentiality as the disclosure of private information in the event of a notification is more to the benefit of the society and less to the benefit of the infected person. According to Mariner, an argument in favor is that “individuals should not necessarily be entitled to control all information about themselves”, just as “a convicted criminal is not able to prevent the fact of his or her conviction from becoming a matter of public record” [34]. The condition of a person suffering from a significantly severe transmissible disease is strongly related to public interest, as it is potentially dangerous for the society and may lead to the infringement of fundamental human rights like the right to life. Additionally, provided public health registries are governed by “strict rules of data protection and confidentiality” [35], the restriction of one’s right to privacy or confidentiality is not actually to be considered infringement of this right when compared to the important benefit for the society. One of the presuppositions for the justification of restrictions in the Siracusa principles [26] worth discussing is whether notification provided in this way, is indeed the least restrictive means. The need to collect identifiable information could be proved, but as the public health goal could be achieved without named identifiers, the latter would be preferable, as it would less invade privacy [33].

The above mentioned ethical issues, related to confidentiality and privacy, are commonly discussed in case of diseases associated with social stigmatization, like TB or AIDS [35] and also arise in cases of a direct or indirect notification of third parties, except for the authorities. Such a direct notification is provided in the Health Protection (Local Authority Powers) Regulations 2010 [36] according to which when a child suffers from an infection or contamination potentially presenting significant harm to public health (like TB) while there is a notice from the local authority that the child be kept away from school, the head teacher should be informed of both the notice and its content. While there may be no doubts as to the necessity of informing the head teacher about such a notice, as it is a way for the authorities to ensure its implementation, the necessity to inform the head teacher of its *full content* may be questionable. In fact, there is no obvious reason why the head teacher should be aware of the specific disease the child suffers from unless their classmates may have already been infected. Even so, the description of the first symptoms or of the way of transmission may be adequate.

3 Contact Tracing

Other provisions that may raise similar objections have to do with the indirect notification of third parties, i.e. in case of contact tracing, which is to identify those exposed to a patient with TB [37]. Collecting information for the investigation of a case of TB raises additional issues concerning the right to privacy. In the Public Health Act 1984 (as amended) [24], it is provided that the required information may refer to the patient’s health, the identity of any related person or other circumstances (contacts, places etc). Contact tracing raises ethical issues concerning the privacy not only of the patient, but also of the individuals whose names are disclosed and who are not presented with the choice whether to release their names to officials or not [38]. In English legislation there is a special provision regarding incidents of severely infectious diseases, like TB, related to contact tracing in

schools. According to this, it is in the local authority's power to require that the head teacher provides them with the names and contact details of the pupils of the school where such an incident has been recorded, in order to clarify whether they are also infected or contaminated [36]. While this provision is very important for the control of a communicable disease among a vulnerable group, like children, the information collected should not exceed the data necessary to control the disease, and the confidentiality of the information should be ensured. It is of paramount importance that the supposedly infected person should not be identifiable. If this is not possible, third parties should at least not be aware of the specific disease the person suffers from, mainly in case of infectious diseases which are related to social stigma, like TB. Another reason why the person should not be identifiable is that the above provision may apply even in case of a probable infection or contamination ("may be infected or contaminated"), which means that they may be stigmatised just because of a hypothesis.

4 Voluntary Cooperation by the Patient and Social Support

In general, individual measures against the will of the person, such as detention, are to be applied only in exceptional circumstances. In most cases, there is no need of a regulatory intervention towards the completion of the treatment against TB even when there are severe social problems [39]. According to the WHO guidelines on ethics concerning TB [14], it is of primary importance as far as the respect of the right to autonomy is concerned before imposing any measure on an individual, as a practice of last resort, that the designated authority tries to obtain their informed consent, after giving them the opportunity to choose from different options. This presupposition is not included in the current legislation, probably because it is provided that an order is made only when necessary for the reduction or removal of a risk. It may be assumed that efforts of voluntary cooperation on the basis of the health professional– patient relationship (provided in detail in the relevant professional codes and legislation) have already failed. Yet, relevant regulations [36] provide that before asking for an order, a local authority may request that a person or group of persons do or refrain from doing anything in order to protect public health from infectious diseases. Voluntary cooperation and adherence to treatment is likely to be more successful in the protection of public health (and the interests of the patient) than any strict legislative restriction on attendance [27], when patients have been given more information on TB, regarding modes of transmission, available treatments and the risks for both themselves and the community in case of no treatment [14].

Although in the explanatory memorandum [27] it is mentioned that "as awareness of the new or revised provisions increases", the use of the compulsory measures provided may also increase, something that could "damage relationships between public health officials and those they deal with - members of the general public, head teachers, parents and employers". To eliminate such a risk, the memorandum suggests that suitable guidance reinforcing health professionals to aim first at the voluntary cooperation of the patient should be created. "Providers should seek to understand the reasons the patient is reluctant about treatment and they should work together to identify methods for overcoming these concerns. It is rare that patients persist in refusing treatment when appropriate counselling is provided" [14]. Mainly in case of TB, whose duration of treatment is long and there may be a need for the patient to abstain from activities for a long period, the patient may be reluctant, for example to be quarantined, due to socioeconomic reasons. It is very important

for patients to be informed about the provisions or measures that are applicable and supportive in their case in order to reassure their concerns.

According to the WHO guidelines on ethics concerning TB “reasonable social supports should be provided to isolated patients and their dependants, taking into account the local system’s capacity” [14]. Legislation in England [40] provides that when compulsory detention, isolation or quarantine have been imposed by an order of a justice of the peace, there is a duty on the part of the local authority responsible for the application of the order, to “have regard to the impact of the order on the welfare” of the patient or of their dependants, for the period during which the order is applicable. This provision ensures that the needs for care or essential services of those whose right to liberty has been restricted and of their dependants will not be adversely influenced by the order [27], safeguarding in this way the right to dignity of both the subject of the order and their family, a right which is strongly related to autonomy.

5 Prior Notification and Information about any Compulsory Measure

When despite all reasonable efforts, the patient insists on refusing treatment or using other suitable measures to avoid the transmission of the disease, he/she should be aware of the possibility of being subject to compulsory isolation or detention [14]. English legislation provides for the duty of the local authority to notify the patient about any application of an order referring to them [40,24]. Such a notification is also extremely important for the respect of the subjects’ rights to dignity, self-determination and autonomy because it enables them to represent their interests before the justice of the peace [27]. The exception [40] of this duty in case of danger of absconding or of undermining the order could be considered reasonable if applied only when necessary, but even in this case the subject should be aware of the possibility that such an order can be made, as this may help them realise the gravity of the situation and persuade them to consent to the action.

In the Health Protection (Part 2A Orders) Regulations 2010 [40] it is provided that the local authorities have a duty to take all reasonable steps to ensure that the subject of the order understands its effect, its reasoning and the power under which it has been made, as soon as it is reasonably practicable. Local authorities also have to ascertain that the subject of the order is fully aware of their right to apply for a variation or revocation of the order and of the relevant support services available and how to contact them. This provision contributes to the respect of the person’s right to autonomy as every person has the right to be informed of what is being done to their body and why [14], let alone being informed of issues related to a restriction or requirement imposed on them. Besides this, the patient’s right to autonomy is respected to a considerable extent as the patient is provided with the appropriate information and is therefore able to make informed decisions concerning their life [41], within the frame set by the order and comply with it [27] or apply for a variation or revocation. The provision of information may also offer a secondary benefit by helping “instil trust in the system” and “respect in the community” which are vital as “trust is essential for public health systems to succeed” [14].

6 Wide range of measures and criteria

The current legislation in England provides for a wide range of restrictions or requirements that may be imposed on people with infectious diseases like TB. It also provides that in order for them to be imposed there should be an order made by a justice of peace. On the one hand, the above may lead to better target measures, flexible and suitable for each case [42], and on the other hand to better protected individual rights [27]. The wide range of available restrictions and requirements may contribute, according to the circumstances, to the imposition of the least restrictive and most proportionate measure provided and to the respect to some of the Siracusa principles [26]. For example, while previously in England [43] the main available measures to be imposed on an adult diagnosed with TB at an infectious stage were the detention of the patient and the request to discontinue their work, now the infected person may be ordered to abstain from working or trading, to refrain from attending an event or gathering, training or counselling sessions on how to reduce the risk of infecting others [24]. Such measures are comparatively much less invasive on individual rights than detention.

In addition, before the imposition of any restriction or requirement by an order several strict criteria (e.g. significant harm to human health [24]) and evidential requirements (e.g. symptoms, diagnosis, outcome of clinical or laboratory tests [40]), clearly described in both primary and secondary legislation, should be fulfilled [27] so that the measure ordered will not be arbitrary, but legal, proportionate and necessary (e.g. “it is necessary to make the order in order to remove that risk”) [24]. Furthermore, it is ensured that “the principle of ECtHR (European Court of Human Rights) case law, that the justification for depriving a person of their liberty must be ‘reliably shown’, is satisfied” [27]. In addition, any restriction of individual rights, even in accordance to the Siracusa principles should only be of limited duration [14]. This additional safeguard is reflected in the UK law with specific time limits (i.e. for a period of maximum 28 days, which may be extended for maximum 28 more days with a second order of a justice of the peace) [24,27,40].

7 Variation or Revocation of an Order

According to the Siracusa principles of the United Nations, every limitation imposed on human rights “shall be subject to the possibility of challenge to and remedy against its abusive application” [26]. In accordance to this principle, the legislation in England provides that the person ‘affected’ from an order, the local authority or any other authority designated to execute or enforce the order in question have the right to make an appeal for its variation or revocation [24]. The above provisions contribute to the respect of human rights either because an order or a notice may have been made arbitrarily or unfairly, despite the safeguards of the legislation, or because conditions related to the order may have changed in the meantime.

Yet, two ethical issues still remain to be further discussed. The first issue has to do with the provision according to which the variation or revocation of an order does not invalidate what has been done prior to it [24]. In our opinion, the content of this provision should be reviewed mainly with reference to the cases when the conditions which lead to the order have not changed but it is still recognised that the order should not have been made. The second issue, which is of a more specific nature, has been raised during the consultation of the relevant legislation and concerns the independent review of a notice regarding the ban

on school attendance [27]. Nevertheless, additional measures to ensure this independence have been considered by the Department of Health impracticable while it has been claimed that “in practice liaison with professionals in the HPA and the relevant primary care trust provides an element of independence in both the original decision and in the review” [27]. The issue, however, is worth further consideration.

8 Detention

The detention of infected persons is one of the most invasive measures for the control of TB in England and most European countries [24]. According to Coker et al [29] the legislation in eight out of fourteen European countries surveyed by the authors, provide for compulsory detention, either in an institution or at home. However, the circumstantial character of this measure is reflected in the WHO guidelines on the ethics of TB [14], where it is mentioned that in some exceptional cases of TB patients, public interest may morally justify their compulsory detention. Issues also arise in relation to the Siracusa principles [26] regarding the necessity and proportionality of such a measure. Martin [44], commenting on a study she conducted with da Lomba [45], claims there is inadequate evidence confirming that detention is an effective and necessary measure for the control of infectious diseases. She explains that in France, where detention was not provided as a measure for the control of diseases during the study, the rate of TB was more stable than the one in the United Kingdom, while other factors related to the incidence of TB, such as the socio-economic conditions and the geographic climate were almost the same. It may be the case that there is probably a need for more scientific data so that an appropriate review regarding the moral justification of compulsory detention can be conducted.

9 Compulsory Treatment

The discussion concerning compulsory treatment should be made on a different basis. Compulsory treatment is rightly not provided for in the relevant regulations, despite the fact that the Health Protection Agency asked for such a provision [42]. Compulsory treatment could not be morally justified on the basis of preventing risk of harm to others, when the risk of transmission of a disease can be addressed by patients’ detention, as on the one hand -mainly in case of TB-, patient’s detention is a presupposition for compulsory treatment while on the other hand it is a less restrictive measure comparing to compulsory treatment. Therefore, compulsory treatment does not meet the presuppositions provided in the Siracusa principles [26] of necessity, proportionality and selection of the least restrictive means required for the achievement of the purpose of the limitation, as the detention itself prevents the transmission of the disease. According to the relevant WHO guidelines, forcing isolated patients to undergo treatment “would require a repeated invasion of bodily integrity” [14]. But even in case of accepting the moral justification of compulsory treatment, this is not the appropriate one in the event of TB. The long duration of the treatment against TB (at least 6 months) [46] and the fact that the disease is not transmissible some weeks after the beginning of the treatment [47] raise concerns over how compulsory treatment will be morally justified after this period [33,48].

10 Conclusion

The control of TB, both its multidrug-resistant form and its “extensively” drug resistant form is a real global challenge nowadays [4,12]. In the UK, as in most high-income countries, TB is mainly related to immigration from high TB burden regions [49] and its control is closely associated with efforts to reduce inequalities and deprivation [50]. In the UK, TB incidence was increasing until 2005 when it started to stabilise, albeit remaining in high levels. Since 2011, TB cases have once more started to show a tendency upwards. During the last decade, a slight increase in first line drug resistance and multidrug-resistance has been observed, mainly in immigrants coming from regions with a high burden of drug resistant TB, such as the Indian subcontinent and Eastern Europe [51]. Despite the fact that there is a wide range of public health measures that could contribute to the control of this disease, there are several ethical concerns relevant to the right to autonomy which hinder their implementation or raise objections concerning their moral justification.

The Public Health (Control of Disease) Act 1984 -as amended by the Health and Social Care Acts 2008 and 2012- and the regulations made under this Act include several provisions for the control of infectious diseases like TB. It is provided *inter alia* that in certain cases compulsory measures (detention, non attendance at school etc) could be imposed and the procedures under which these measures could be varied or revoked are described.

Those provisions imposing compulsory measures are generally in accordance with the main international texts safeguarding the protection of human rights, namely the WHO guidelines on ethics of TB prevention, care and control [14] and the Siracusa principles as formulated by the United Nations in 1985. Yet, there are still several slight changes in the legislation which could improve the respect of the right to autonomy by taking into account the social stigma following the diagnosis of TB but also the evidence that other countries which have an even more favourable legislative framework for the respect to the right to autonomy, do not sacrifice anything in the control of TB [45].

In general, it could be claimed that the current legislation for the control of TB in England keeps a delicate balance between the right to autonomy and the need for the protection of public health. The discussion on whether a public health measure is morally justified has deep historical and political roots regarding the conflict of personal autonomy and community welfare. More scientific data on the necessity and effectiveness of the compulsory measures, such as detention for the specific disease, would be helpful for a consensus to be reached.

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