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Nudging, informed consent and public health: Dangerous liaisons between law and neuroscience or opportunity for the future?

Abstract: Italian Law 219/2017 has been a major achievement in the path to recognize the primacy of informed consent as a part of a wide-ranging relationship between physician and patient (therapeutic alliance). In this context many questions arise from neuroscience findings, and two seem to be more significant. The first one is if informed consent may be thought as a result of biochemical processes and how it could be therefore addressed in both health and legal context. The second question stems from the implementation of nudging techniques in public health policies: is nudging an ethical mean to reach a higher level of health in our societies? A comprehensive and multi-disciplinary approach is adopted in order to offer possible answers. The article suggests how informed consent may be regarded as a free choice and why to design a choice architecture that influences citizens' behavior is undoubtedly efficient, but policy-makers have primarily to place weight on building a relationship of trust with people.

Keywords: Nudging — Informed Consent — Bioethics — Public Health — Law 219/2017

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Therapeutic alliance: respect for autonomy as keystone in doctor-patient relationship

In recent years medicine has been characterized not only by enormous advances both in clinical and in research field, but also by a radical renovation of doctor-patient relationship. Historically, roots of the doctor-patient relationship must be sought further back in time and namely in the Greek Enlightenment (or Fifth-Century Enlightenment). Starting with the Hippocratic Oath, a specific attitude towards the patient emerged, whose hallmark is the ethical principle of *beneficence*¹.

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1 'The regimen I adopt shall be for the benefit of my patients according to my ability and judgment, and not for their hurt or for wrong. Whatsoever house I enter, there will I go for the benefit of the sick'; see Kaba and Sooriakumaran 2007: 58.

In this regard, physicians have acted over centuries in order to promote welfare of their patients, but under the assumption that medical expertise and knowledge were unavoidable conditions of a rightful mismatch in the relationship with them. Thus, beneficence has become the breeding ground for the ‘doctor-knows-best’ model; this means that paternalism may be regarded as hardline beneficence², similar to parent-infant relationship in which “the doctor’s role involved acting in the patient’s best medical interests, with doctors regarding a ‘good patient’ as one who submissively accepted the passive role of the infant”³.

But the paternalistic model has been challenged during the last thirty years with critics proposing a more active and autonomous role for patient, and narrowed physician dominance. Thereby patient-centeredness has become increasingly commonplace in medical care and in bioethical debate⁴, with the aim of placing therapeutic alliance between physicians and patients at the core of their relationship⁵. Given the gap of knowledge, expertise, and competence between the healthcare professional and her patient, formerly the asymmetric interaction is unchanged. Nevertheless, assuming therapeutic alliance as paradigm entails questioning patient’s perception of the treatment offered, cognitive components of the choice, and agreement over the purposes of the therapy⁶. Therefore, nowadays alliance between doctor and patient is grounded in co-operation, and patient-centered care has replaced doctor-dominated relationship thus avoiding that the exercise of power misrepresents the decision-making process on either side⁷.

In this setting, wherein the physician has to bridge the gap between medicine and common life, a key role in building therapeutic alliance is played by the legal institution of informed consent. By definition, informed consent “is a process by which the treating health care provider discloses appropriate information to a competent patient so that the patient may make a voluntary choice to accept or refuse treatment”⁸. For informed consent to be valid is required that the patient is competent, adequately informed, and not coerced. Thus, implying not merely beneficence as ethical principle for physician’s action, but mainly the respect for autonomy of the patient, that is freedom to choose and behave when no constraints by others occur. Consequently, powerful therapeutic alliance is rooted in strong process of communication whose aim is to achieve a truly informed consent, by preserving and strengthening trust between physician and patient⁹.

2 Hellin 2002.

3 Kaba and Sooriakumaran 2007: 59.

4 Mead and Bower 2000.

5 Therapeutic alliance relies on cooperation between clinician and patient, their affective connection, and agreement on treatment’s aims. A powerful therapeutic alliance yields successful treatment outcomes such as reduced symptoms, bettered health status and satisfaction with healthcare; see Zambelli Pinto *et al.* 2012.

6 Roth and Fonagy 1996.

7 Kaba and Sooriakumaran 2007: 65.

8 Cocanour 2017: 993; see also Appelbaum 2007.

9 Cocanour 2017.

Recently, the decision-making model at the basis of informed consent has been turning into a shared one, wherein physician and patient seek to manage information. Indeed, the former is committed in translating technical notions in common language, and the latter strives in weighing information with overwhelming emotions and anxiety. In this respect, Italian Law 219/2017 has been a major achievement in the path to recognize the primacy of informed consent as a part of a wide-ranging relationship between physician and patient. As stated in article 1-paragraph 2, the doctor-patient relationship of care and trust must be promoted and valued, since well-grounded in respect for autonomy. Furthermore Law 219/2017 sets communication time as care time (art. 1, par. 8), thereby pointing out how essential is a trustful and truthful disclosure as part of health care. Nevertheless, the Law outlines how the distinctive feature of treatment planning should be shared decision-making, whose outcomes should be complied by health professionals. Hence, respect for autonomy and communication play the leading role in building a powerful therapeutic alliance, designed to provide a satisfactory answer to the demand for healthcare.

Do neuroscience findings challenge informed consent?

It has been stressed the relevance of informed consent in therapeutic alliance between physician and patient, based ethically and legally on respect for autonomy, that means health care provider must disclose information in a truthful and plain way ensuring patient to develop a voluntary choice to refuse or accept treatment. Therefore, it can be reasonably argued that a reflection on freedom of choice should be addressed to shed light on the value of informed consent. In particular, we refer to the innermost conditions that affect consent, setting aside social, cultural and economic aspects of influence.

Indeed, the astonishing results achieved in cognitive sciences and neurosciences in recent decades have led to resurfacing concern over the status of free will, since the investigation on cognitive phenomena has become reality. Starting with the first neurophysiological trials, headed by Benjamin Libet, on the connection between cerebral activity and conscious intentions to move¹⁰, neuroscientific research has made advancements in leaps and bounds. The most recent findings in the field have made feasible for some scientists and philosophers to argue that all facets of the human mind could be reduce to the electro-chemical processes occurring in brain. There also exists a trend of thought and research which traces origins of human behavior in genetics, inasmuch as brain functioning would result from the shape that genetics provides to the organ itself¹¹. Consequently, someone suggests that relevant mutations could arise not only in our intuitive notions of freedom,

10 Libet *et al.* 1983; Libet 2004. It has to be said, however, that severe limitations to Libet's experiments have been highlighted by some scholars; see Baumeister *et al.* 2019 (defining trial's setting 'unrealistic' and 'contrived'): 234; Roskies 2019: 68; Magni 2019: 55; Radder and Meynen 2013; Seifer 2011; Pockett 2006.

11 Cf. Rose 1995; Magni 2019: 50.

but even in legal definition of it. Needless to itemize, informed consent would be involved in this paradigm shift.

Despite of the considerable amount of available neuroscientific studies, there is still no consensus about the feasibility to apply the concept of 'free will' both to action and volition. Nonetheless, it may be pointed out the consensus reached on two conditions by the great majority of authors engaged in the debate. In fact, when dealing with freedom of will, authors concur on assuming that the agent should have alternative courses of action, and the choice among these courses should be based on autonomous and rational resolution¹². It is obvious that, if we assume these conditions as essential, consequently we should consider the distinctive framework where-in human action takes place. It comes down to a venerable metaphysic enigma about the structure of our universe or, in other words, to the ancient dilemma between determinism and indeterminism. Are all events, even moral choices, wholly determined by previously existing causes? Or, conversely, they randomly occur? Indeed, if the world we live in is considered to be determined, freedom is possible only if coupled with commitment (theory of compatibilism/soft determinism). Otherwise, or freedom of will is an illusion (incompatibilism/hard determinism), or determinism is a false metaphysical assumption (libertarianism)¹³.

Either way, someone claims that regarding free will, determinism is not the aspect to ponder on. I refer to Roskies' stance on how, even if the dilemma of determinism was solved, this would not settle the question about the existence and the value of free will. In fact, if intuitively we are brought to think that human volition is free to the extent that the world is not determined or pre-determined, it is reasonable to call into question the value of freedom of will whenever indeterminism is assumed. In other words, how can we talk of freedom of will if the events we are supposed to trigger, or whose courses are supposed to be determined by ours, are perfectly random?¹⁴ In this regard, Roskies contends that neuroscience will always remain silent in the matter of answering to the question if the universe is deterministic or not, but neuroscientists will probably show if brain, instead, is¹⁵. This means that "at some higher level than the motions and interactions of atoms and molecules, low-level indeterminacies wash out and the high-level operation of the system can be characterized by laws, so that its future activity can be reliably predicted on the basis of its past activity"¹⁶. Apart from the ability of neuroscience to tell if human beings are or not deterministic systems, Roskies argues that pondering on determinism is anyway the wrong direction which to look at. The author claims that regardless to the deterministic nature of universe, moral agents may be free or not in their resolutions and that the evaluation of degree of freedom and moral responsibility requires factors other than determinism¹⁷.

12 De Caro and Lavazza, 2019: XIII.

13 Roskies 2006.

14 Roskies 2019: 52.

15 Roskies 2006.

16 *Ivi*: 421.

17 Roskies 2019.

Setting aside determinism, Roskies sustains that the neurological decision-making model provided for movement (decision to move an arm) and choice not including values (statement of the *presence* of a material object) may be applied also to complex, propositional and discursive decisions including value (provision or denial of informed consent). Although, author suggests that to refine the model, more scientific research and imagination for its structure are still needed¹⁸. Anyway, in this threshold-based activation model, different neuronal populations represent consistent deliberations competing with each other. In this outline, agents react in accordance to reasons and on account of reasons, notwithstanding how complex and propositional they are. In short, the neuronal system weighs pros and cons of competing alternatives, by evaluating information on facts and eventual reward. This means that nowadays neuroscientific findings are consistent with our intuitive notion of freedom of will, and that a more refined threshold-based activation model could serve as pattern even for decision making process involving choices not neutral with respect to value¹⁹.

Given this setting, Roskies disagrees with the view requiring consciousness during the whole decision-making process, but she proposes to interpret consciousness in freedom of will as the possibility for agents to access the semantic content of the reasons in accordance to which and on account of which they act. Albeit, the way this occurs is one of the deepest mysteries of science, since neuroscientists nowadays have no clue on *what* and *where* to seek mechanisms responsible for the representation of the most abstract status of human mind²⁰. Nevertheless, Roskies argues that consciousness of the reasons is not enough to reveal consciousness of decision-making process (spectator position). Given that the evaluation of pros and cons is assumed to be held by neuronal process, even joining the reasons at the basis of the decision is not enough. Hence, Roskies claims that consciousness demands *commitment* or, in other words, self-ascribed reasons understood to be consistent with agent's values. Self-consciousness is therefore needed, insofar as the agent should assess the consistency of reasons in relation to her interests, projects and history²¹. Roskies' stance entails the consideration on how little has been explained by neuroscientists about self-representation and self-consciousness apart from the bodily one.

Assuming Roskies' view of consciousness of decision-making process and freedom of will may be useful in order to reflect upon worth and validity of informed consent. That is, to acknowledge that nowadays neuroscience lacks of sharpness and extent of information essential to demonstrate if actually the whole human mind could be explained on a par with electro-chemical processes. And, as a consequence, that our intuitive notion of freedom of will could not be radically shifted. Namely, informed consent as legal institution based on competence, information and voluntariness might be challenged by the most recent neuroscientific

18 *Ivi*: 60.

19 *Ivi*: 64.

20 *Ivi*: 67.

21 *Ivi*: 68.

findings, but it could not be deconstructed. Considered the threshold-based activation model, in reference to the decision-making process at the basis of informed consent, we might claim that different neuronal populations represent competing deliberations such as provision or denial of consent. Thus, the neuronal system weighs pros and cons of the choice, by evaluating risks, benefits and side-effects of a given treatment. As evidence of consciousness for informed consent, it may be reasonably argued that self-ascribed reasons should be consistent with agent's perception of quality of life, future life projects and risk tolerance.

Thereby, the state of the art in neuroscience nowadays is not yet in such a position to radically affect our intuitive notion of freedom of will, even when regarded as a condition to informed consent. In particular, advancement in cognitive science and neuroscience still lack of sharpness to demand a transformation of actual legal institution of informed consent. That is especially the case of the Italian legal system, which recently welcomed Law 219/2017 as an authentic milestone in the acknowledgement of the relevance of self-determination of patient. Doctor-patient relationship, as nowadays designed – in accordance with the ethical principle of respect for autonomy and the criterion of patient-centeredness – is the most undeniable achievement of contemporary medical science, beyond research and technical outcomes. If in the future neuroscientists will demonstrate the reduction of whole human mind to biochemical processes, then philosophers, bioethicists and lawyers will be asked to address the foundations of many legal institutions and informed consent will obviously be one of those.

Dangerous liaisons between nudging techniques and informed consent

Before a patient can provide an authentic consent, she should understand alternative choices, risks, benefits, and side-effects stemming from a treatment. It is therefore obvious that doctor-patient relationship retains its asymmetrical nature, since most patients need physicians to educate and lead them. Asymmetry includes both expertise knowledge and emotional condition, given that patients may experience anxiety, distress, and fear. Over the centuries these features were simply solved (or ignored) by implementing the ethical principle of *beneficence* and, consequently, physicians paid great attention to promote welfare of their patients, but with plain acceptance that medical expertise and knowledge were unavoidable conditions of a rightful mismatch in the relationship with them. Thus the 'doctor-knows-best' model, or hardline beneficence, prevailed until late 80s. As mentioned above, nowadays doctor-patient relationship is based on patient-centeredness, but, given the undeniable imbalance among parties, it may be a worthwhile question the one concerning how to improve quality of choice for patients. Moreover, many patients are supposed to refrain from the option regarded as best by their physician, meanwhile many clinicians concern about their patients make irrational healthcare decisions, driven by emotional burden stemmed from illness.

Here I suggest to question the potential role of *nudging* with regard to informed consent. Thaler and Sunstein describe a nudge as "any aspect of the choice ar-

chitecture that alters people's behavior in a predictable way without forbidding any options or significantly changing their economic incentives. To count as a mere nudge, the intervention must be easy and cheap to avoid. Nudges are not mandates"²². That is, considering how the context wherein agents make decisions (choice architecture) may be designed to influence their behavior or, in this particular case, to provide consent to the option the physician considers is best²³. Nudging falls into the category of strategies suggested by libertarian paternalists, who claim that is feasible and morally acceptable to influence an agent's behavior to benefit him without infringing on his autonomy²⁴. "Libertarian paternalists see countless opportunity for improving people's health"²⁵, and creating a specific choice architecture for informed consent is definitely one.

According to Thaler and Sunstein, our intuitive notion of freedom of choice is biased by a false assumption, that is "almost all people, almost all of the time, make choices that are in their best interests or at the very least are better than the choices that would be made by someone else"²⁶. This assumption is proven to be false insofar as agents are situated in context wherein, they are "inexperienced and poorly informed, and in which feedback is slow or infrequent"²⁷. Consequently, it is feasible to imagine that agents are most likely to need nudges for choice characterized by complexity, hardship, and infrequency. In parallel, choice architects are supposed to take better decisions insofar they are more expert than the agents to influence, and agents' interests or needs can be easily acknowledged²⁸. The authors also argue that sometimes nudging is unavoidable and that forms of paternalism devoid of coercion do exist²⁹.

These reflections raise a legitimate question: is it feasible and ethically acceptable to influence patient's choice by creating a choice architecture designed to provide consent to the option the physician detect as best? Libertarian paternalists answer positively, since patients are required to make decisions which are complex, infrequent, and rich in information previously unknown, whereas physicians are supposed to easily identify patients' needs and interests in the matter. However, libertarian paternalism entails low-cost opt-out rights, this meaning that the kind of influence exercised on patients must preserve at least, or increase, freedom of choice. That is, 'doctor-knows-best' model is not consistent with nudging.

In this setting, philosophers have proposed a range of influences to nudge patients towards providing consent to the physician's favored option, since many physicians staunchly believe they have a moral obligation to foster their patients'

22 Thaler and Sunstein 2003; Thaler and Sunstein 2009: 6.

23 Thaler and Sunstein 2009; Cohen 2013 (a); Cohen 2013 (b); Cohen 2015; Douglas and Proudfoot 2013; Munoz *et al.* 2015.

24 Thaler and Sunstein 2003.

25 Thaler and Sunstein 2009: 159.

26 *Ivi*: 9.

27 *Ibidem*.

28 Thaler and Sunstein 2009: 250.

29 *Ivi*: 10-11.

health, but they are concerned this obligation reveals in conflict with obtaining a genuine informed consent³⁰. Conflicts may arise for many reasons, even though physician discloses thoroughly information and she proves to be forthcoming. Nonetheless, patient may withhold some information, or she may value things unlike physician does, or she may even make irrational choice, driven by anxiety, mistrust or fear³¹. Regarding nudging and informed consent, philosophers are split. Some philosophers argue that when it concerns to secure informed consent, nudging is essential³² and unavoidable³³, instead others argue that nudging is inconsistent with adequate disclosure, which is assumed to be thorough truth-telling³⁴.

Hence, philosophers have offered a range of influences to nudge patients during physicians' adequate disclosure. Simkulet discusses eight of those influences and acknowledges just three as nudges, while arguing that one nudge and the other influences are wholly deceiving forms of disclosure, *a priori* incompatible with securing informed consent. The first nudge is *discouraging disclosure*, that means ordering options in a way patient is influenced to choose the physician's preferred one or, alternatively, annoying patient by providing information rich in technical terminology, data or trivial elements. In so doing, physician hides relevant information she does not desire the patient to listen. In this respect, the aim of "nudging is not to have the patient understand her options so that the patient can make a reasonable, informed decision. Rather, the physician nudges because although the patient is competent, he does not trust the patient to consent to the option he thinks best, and seeks to predictably alter the patient's behavior through means other than giving her reasons"³⁵. The second nudge consists of making recommendations, insofar as they are honest. In fact, providing recommendations without nudging is almost unfeasible, since in standard medical practice physicians are required to advise their patients and to recommend best options, avoiding they remain neutral³⁶. The third nudge corresponds with offering options, given that patients turn out to be influenced by the options they were presented with. Douglas and Proudfoot describe a trial wherein physician adds a not valid medical option to the list of the valid ones and many patients came to believe it was recommended just because it was mentioned³⁷. Therefore, this may be considered as nudging, but it violates the truth-telling condition at the basis of adequate disclosure, since a not valid option, potentially harmful, is mentioned. As a consequence, it is not consistent with securing valid informed consent.

Simkulet does not regard as nudges other influences proposed by some philosophers, such as narrowing disclosure, refusal of a treatment, projecting optimism,

30 Simkulet 2019.

31 *Ibidem*.

32 Douglas and Proudfoot 2013; Munoz *et al.* 2015.

33 Brooks 2013.

34 Simkulet 2019.

35 *Ivi*: 173.

36 Douglas and Proudfoot 2013

37 Douglas and Proudfoot 2013.

physician's appearance, and framing information. Indeed, narrowing disclosure entails deception of patient about her options, *a priori* hidden by physician, with no low-cost opt-out rights for patient. Similarly, physician deceives patient by dishonestly refusing a treatment, that is by forbidding a valid option without justified medical reasons. Moreover, if during disclosure physician conveys optimism – even though nonverbally – when she is actually not optimistic, then this kind of influence is incompatible with truth-telling and securing informed consent. As well physician's appearance may not be considered nudge, even if wearing scrubs improves patient's trust and thus chances of consent, as Cohen stresses, the doctor “has to wear *something*”³⁸. Lastly, framing information in an honest way may not be regarded as nudge since it is merely a means for physician to explain expected outcomes, for instance in order to make patient understands success and failure rates³⁹.

I would definitively advocate Simkulet's perspective by arguing that nudging is not consistent with informed consent, unless we assume that securing informed consent does not need truth-telling, that the goal of truth-telling is narrow – that is sufficient for the patient to understand *what* physician says, but not *why* -, and finally that a different notion of truth-telling is offered⁴⁰. Hence, in contemporary notion of doctor-patient relationship, grounded in patient-centeredness, nudging towards informed consent is not ethically acceptable. Since nudging, in this setting, can leave room for wariness, mistrust, and lack of confidence. Nonetheless, as regards ethical principles, the threat of hard-beneficence resurgence is undeniable. That is, the ‘slippery slope’ critique seems adequate when it comes to informed consent and to the specific doctor-patient relationship, unavoidably characterized by asymmetry. In other words, concerns arise that libertarian paternalism slides down into hardline beneficence and paternalism *tout-court* and thus coercion, since no low-cost opt-out rights seem feasible when it concerns informed consent.

Why and how to implement nudging techniques in public health policies

A number of potential implementations of nudging are still feasible in health sector. Indeed, even Simkulet argues that nudging may be used in a wide range of medical contexts to promote healthy behavior⁴¹. In these pages, I argue that nudging might be profitably implemented at a public health policy level, setting aside informed consent and the specific therapeutic alliance between physician and patient.

As mentioned above, “Libertarian paternalists see countless opportunity for improving people's health”⁴², such as designing public policies to influence citizens' behavior in order to promote, to improve, and to increase their level of health. This

38 Cohen 2013 (a): 9.

39 Simkulet 2019.

40 *Ibidem*.

41 E.g. Financial incentives for patients for getting regularly checked, prominent display of medical posters or pamphlets etc.; Simkulet 2017.

42 Thaler and Sunstein 2009: 159.

kind of policies are not supposed to be built and implemented through traditional regulatory mechanism, but by crafting an architecture of choice which facilitates some behaviors than others and without any compulsion. In fact, the discouraged conduct is perfectly legal, even though who performs it is burdened with economic, psychologic, and social costs⁴³. According to libertarian paternalists, these costs stem from what is considered a suboptimal decision due to bounded rationality. In this setting, suboptimal decision is such when its outcomes for agent or society in general are limited, and therefore nudging may become useful tool to reduce the lack of rationality by mildly pushing individuals towards their best interests, without denying them the chance of making different choices⁴⁴.

Beyond theoretical level, nudging has already made his entrance in public health policies and, according to Thaler and Sunstein, this is almost unavoidable. In fact, default terms in health regulations do not “come from nature or from the sky”⁴⁵: government cannot be absent when it concerns regulations and public policies’ design. This is particularly true if we think of organ donation, gamete donation, preventive healthcare, public service advertises, and shocking images on cigarette packs. In all these fields sweet persuasion already has an essential role. Let us take the example of organ donation and, more specifically, the regulations on consent to donate. Most States have legislations providing for ‘explicit consent rule’, that means people must be proactive if they want do donate their organs post-mortem. In Italy, citizens who intend to donate their organs have a wide range of options. They may sign particular forms pre-arranged by local healthcare authorities or by register offices. Otherwise, Health Ministry and nonprofit organizations supply interested individuals with distinctive cards suitable for the declaration of consent. Moreover, to express consent, it is feasible filling in a handwritten document, supplied by the Italian Association for Organ Donation or even on ordinary paper, which has to be guarded between personal papers. In short, Italian legislation is based on the ‘just-maximize-choices’ model to favor freedom of choice, which is standard policy advice. But, Thaler and Sunstein have thoroughly demonstrated this is a false assumption, since even in a ‘one-click’ world, where crucial choice can be made online, without any waste of time or barrier, the default rule prevails. In our example, the default rule consists of not being a donor, since a proactive choice is required to provide consent. Without coming to ‘routine removal’ model, that means “the State owns rights to body parts of people who are dead or in certain hopeless conditions”⁴⁶, it can be argued that an appropriate nudging technique to increase donors’ number would consist in ‘mandated choice’ model. This model provides for compulsion of choice, by forcing citizens to make a free decision regarding organ donation, for example when they have to renew their papers, as Illinois has required since 2006⁴⁷.

43 Leone 2016.

44 Tallacchini 2017.

45 Thaler and Sunstein 2009: 241.

46 Thaler and Sunstein: 179.

47 Thaler and Sunstein: 182.

Nowadays policy makers feed growing attention to nudging in particular for healthcare problems resistant to different approaches, such as decisions about vaccination. Over the decades mandatory vaccination has proven effective at increasing the number of people vaccinated, even though it entails ethical concerns for healthcare professionals and, in the last few years, it has resulted in loud protests of anti-vaccination movement. Vaccine hesitancy is rooted in cognitive biases extremely relevant in the setting of decision-making process. First, ‘omission bias’, which leads agent to prefer an omission (potentially harmful) to an act (potentially less harmful). Second, ‘ambiguity aversion’ as the attitude to prefer a known risk (no treatment) to an unknown one (unclear treatment). Third, ‘present bias’, which describes how agent gives greater weight to present costs and benefits than to the future ones. Then, optimism plays an essential role, since agents show tendency to believe that health problems occur easier to other people than to themselves. Lastly, naturalness bias leads agents believe that natural substances are anyhow preferable to synthetic options⁴⁸. In the setting of decisions about influenza vaccination “a successful strategy for policy-makers and others hoping to increase vaccination rates is to design a “choice architecture”. [...] These nudges incentivize vaccinations and help better align vaccination intentions with near-term actions”⁴⁹. Questioning if nudges may be implemented to increase vaccination is now, more than ever, essential. Indeed, the spread of SARS-CoV-2 infection has already raised both ethical and legal questions about a hypothetical vaccine compulsoriness.

Given these examples, goals of nudging emerge, namely maximizing rationality of individuals by influencing their choices and maximizing welfare in general or health in particular. But, these goals in themselves are not sufficient to ethically justify the implementation of nudging in public health policies and regulations. Here I argue, by following in the footsteps of Tallacchini, that to be ethically acceptable, nudging must have sharply defined and social admissible purposes. Furthermore, nudges must be built with another guiding principle: transparency⁵⁰. Transparency is, to all intents and purposes, the keystone of the implementation of nudging in public health policies. This is relevant insofar as public policies should be designed taking into account the relationship of trust between citizens and public institutions, especially when it comes to healthcare.

Then, Tallacchini sheds light on which might be a proper place for nudging in public health policies and regulations. In particular, if at the basis of public policy there is scientific uncertainty, then nudging should be avoided, since when it is implemented it entails steering information. Moreover, the author claims the relevance of civic and medical education for citizens, in order to create a ‘cooperative right’ to health. Nonetheless, trust between institutions and citizens should not be taken for granted, but instead it must be place at core level of an on-going

48 Dubov and Phung 2015.

49 Dubov and Phung 2015: 2534.

50 Tallacchini 2017. The importance of transparency or ‘publicity principle’ is also highlighted by Thaler and Sunstein referring to Rawls’ theory; see Thaler and Sunstein 2009.

process⁵¹. In this respect, a participative based form of the regulatory process is advocated, insofar as public engagement yields awareness about the implementation of sweet persuasion tools. Under these conditions, nudging may effectively play an ethically acceptable role in healthcare regulations.

Conclusion

In these pages, I proposed few reflections on interweaving of law and neuroscience, with particular focusing on informed consent, nudging techniques and public health policies.

Considered how doctor-patient relationship has changed over centuries, we are allowed to identify patient-centeredness as the model of the contemporary 'therapeutic alliance' between physicians and patients. This alliance is grounded in respect for autonomy as key ethical principle, and constituting besides the condition of legitimacy of the relation between people (regarded both as citizens and patients), healthcare professionals and public institutions. Respect for autonomy provides moreover the ethical basis for the legal institution of informed consent, in virtue of which healthcare provider must disclose information in a truthful and plain way ensuring patient to develop a voluntary choice to refuse or accept treatment.

Therefore, it can be reasonably argued that a reflection on freedom of choice should be addressed to shed light on the value of informed consent. Assumed Roskies' view of consciousness of decision-making process and freedom of will might be useful in order to reflect upon worth and validity of informed consent. That is, to acknowledge nowadays neuroscience lacks of sharpness and extent of information essential to demonstrate if actually the whole human mind could be explained on a par with electro-chemical processes. Consequently, our intuitive notion of freedom of will could not be radically shifted and, thus, informed consent as legal institution based on competence, information and voluntariness might be challenged by the most recent neuroscientific findings, but it could not be deconstructed.

Maintained informed consent in its contemporary understanding, we might wonder if is it feasible and morally acceptable to influence patient's choice by creating a choice architecture designed to provide consent to the option the physician detects as best. Libertarian paternalists answer positively, since patients are required to make decisions which are complex, infrequent, and rich in information previously unknown, whereas physicians are supposed to easily identify patients' need and interests in the context. Implementation of nudging techniques towards securing informed consent stems from finding that demonstrates many patients refrain from the choice that their physician regards as best, meanwhile many physicians worry that their patients make irrational healthcare choices, undermining chances of efficient healthcare. But, in the specific and distinctive context of in-

formed consent, concerns arise that libertarian paternalism slides down into hard-line beneficence and paternalism *tout-court* and thus coercion, since no low-cost opt-out rights seem feasible when it concerns informed consent.

Anyway, a number of potential implementations of nudging are still feasible regarding health. Beyond theoretical level, nudging has already made his entrance in public health policies and, according to many philosophers, this is almost unavoidable. From organ donation to vaccination, nudging techniques may offer a valid opportunity for the future, especially in those healthcare fields that have proved resistant to other approaches. To be ethically acceptable, nudging must have sharply defined and social admissible purposes. In this setting, nudges must be built with transparency as guiding principle, insofar as public policies should be always designed on the basis of the relationship of trust between citizens and public institutions, but especially when it concerns healthcare. Furthermore, relevance of medical education for citizens has to be strengthened, in order to create a ‘cooperative right’ to health and give concrete meaning to ‘therapeutic alliance’ founded on informed consent. In this respect, trust between institutions and citizens must be placed at core level of an on-going process.

In this perspective the interweaving of law and neuroscience, taking into account informed consent, nudging techniques and public health policies, could yield worthwhile outcomes both for individuals and society. This meaning not a mere maximization of rational choices and health, but mostly a participative process to design choice architecture for public policies and regulations in health sector. Thereby, law and neuroscience in health regulations might give rise not to dangerous liaisons, but genuine opportunity for the future.

References

- Appelbaum, P.S. 2007, “Assessment of patient’s competence to consent to treatment”, *The New England Journal of Medicine*, 357, 1834-1840.
- Baumeister, R.F. et al. 2019, “Per le azioni umane complesse e necessaria la coscienza”, in De Caro, M., Lavazza, A., Sartori, G. (ed.), *Siamo davvero liberi? Le neuroscienze e il mistero del libero arbitrio*, Torino: Codice Edizioni, 225-235
- Brooks, T. 2013, “Should we nudge informed consent?”, *American Journal of Bioethics*, 13(6), 22-23.
- Caruso, G.D. 2012, *Free Will and Consciousness: A Determinist Account of the Illusion of Free Will*, Lanham (MD): Lexington Books.
- Cocanour C.S. 2017, “Informed consent — It’s more than a signature on a piece of paper”, *The American Journal of Surgery*, 214, 993-997.
- Cohen, S. 2013 (a), “Nudging and informed consent”, *American Journal of Bioethics*, 13(6), 3-11.

- Cohen, S. 2013 (b), “Nudging in context: Response to open peer commentaries on “nudging and informed consent”, *American Journal of Bioethics*, 13(11), 1-6.
- Cohen, S. 2015, “A philosophical misunderstanding at the basis of opposition to nudging”, *American Journal of Bioethics*, 15(10), 39-41.
- De Caro, M. and Lavazza, A. 2019, “La libertà nell’era della scienza”, in De Caro, M., Lavazza, A., Sartori, G. (ed.), *Siamo davvero liberi? Le neuroscienze e il mistero del libero arbitrio*, Torino: Codice Edizioni, VII-XXX.
- Douglas, C. and Proudfoot, E. 2013), “Nudging and the complicated real life of “informed consent””, *American Journal of Bioethics*, 13(6), 16-17.
- Dubov, A. and Phung, C. 2015, “Nudges or mandates? The ethics of mandatory flu vaccination”, *Vaccine*, 33, 2530-2535.
- Hellín, T. 2002, “The Physician-patient relationship: recent developments and changes”, *Haemophilia*, 8(3), 450-454.
- Kaba, R. and Sooriakumaran, P. 2007, “The evolution of the doctor-patient relationship”, *International Journal of Surgery*, 5, 57-65.
- Leone, L. 2016, “Sulle spinte gentili del *nudge*: un quadro d’insieme. Più libertà o nuovo paternalismo?”, *Epidemiologia e Prevenzione*, 40(6), 462-465.
- Libet, B. 2004, *Mind Time: The Temporal Factor in Consciousness*, Cambridge (MA): Harvard University Press.
- Libet, B. *et al.* 1983, “Time of Conscious Intention to Act in Relation to Onset of Cerebral Activity (Readiness-Potential): The Unconscious Initiation of a Freely Voluntary Act”, *Brain*, 106, 623-642.
- Magni, S.F. 2019, *L’etica tra genetica e neuroscienze. Libero arbitrio, responsabilità, generazione*, Roma: Carocci.
- McGinn, C. 1993, *The Problems of Philosophy*, Oxford: Blackwell.
- Mead, N. and Bower, P. 2000, “Patient-centredness: a conceptual framework and review of the empirical literature”, *Social Science & Medicine*, 51, 1087-1110.
- Munoz, R. *et al.* (2015), “Evidence-based nudging: best practices in informed consent”, *American Journal of Bioethics*, 15(10), 43-45.
- Pockett, S. 2006, *The Neuroscience in movement*, in: *Does conscious cause behavior?*, ed. Pockett, S., Banks, W.P., Gallagher S., Cambridge (MA): MIT Press, 9-24.
- Radder, H. and Meynen, G. 2013, “Does the brain “initiate” freely willed processes? A philosophy of science critique of Libet-type experiments and their interpretation”, *Theory and Psychology*, 23(1), 3-21.

- Rose, S. 1995, "The Rise of Neurogenetic Determinism", *Nature*, 373, 380-382.
- Roskies, A.L. 2006, "Neuroscientific challenges to free will and responsibility", *TREND in Cognitive Science*, 10(9), 419-423.
- Roskies, A.L. 2019, "Esiste la liberta se decidono i nostri neuroni?", in De Caro, M., Lavazza, A., Sartori, G. (ed.), *Siamo davvero liberi? Le neuroscienze e il mistero del libero arbitrio*, Torino: Codice Edizioni, 51-69.
- Roth, A. and Fonagy, P. 1996, *What works for whom?. A critical review of psychotherapy research*, London: Guildford.
- Seifert, J. 2011, "In defense of Free Will: A Critique to Benjamin Libet", *The Review of Metaphysics*, 65(2), 377-407.
- Simkulet, W. 2017, "Nudging, informed consent and bullshit", *Journal of Medical Ethics*, 44, 536-542.
- Simkulet, W. 2019, "Informed consent and nudging", *Bioethics*, 33, 169-184.
- Smilansky, S. 2000, *Free Will and Illusion*, Oxford: Oxford University Press.
- Tallacchini, M. 2017, "Nudging o educazione a scelte civiche responsabili? L'esempio dello screening della mammella", *Epidemiologia a Prevenzione*, 41(1), 14-19.
- Thaler, R.H. and Sunstein, C.R. 2003, "Libertarian paternalism", *American Economic Review*, 93, 175-179.
- Thaler, R.H. and Sunstein, C.R. 2009, *Nudge. Improving Decisions About Health, Wealth, and Happiness*, London: Penguin Books.
- van Inwagen, P. 1983, *An Essay on Free Will*, Oxford: Oxford University Press.
- Zambelli Pinto, R. et al. 2012, "Patient-centred communication is associated with positive therapeutic alliance: a systematic review", *Journal of Physiotherapy*, 58, 77-87.