Toward personalized informed consent in cancer care

That was when I learned that words are no good; that words don't fit

ever fit even what they are trying to say at.

William Faulkner, *As I Lay Dying* (1930)

Faulkner's words provide my point of entry for consideration of the articles in this special issue of *Medical Anthropology*. The quotation highlights the controversial relationship between language and experience and calls into question the capacity of talk and language to *say* any experience. As the articles in this volume show, people with cancer may experience profound emotional distress, bewilderment and loss, and are often challenged to engage in life while living with symptomatic disease and closeness to death. This circumstance may dramatically alter support needs and personal relationships, threaten psychological well-being and present challenges for patients and families to *say* and navigate a complex health care system. The papers present different facets of the profound uncertainty and unpredictability that characterizes 21st century cancer care for patients and clinicians. To me the articles reflect patients' and health care professionals' struggle with the risk calculus involved in consenting to treatments where outcomes are unproven, a struggle that has recently been embellished by the uncertainty of COVID-19.

Choice and consent are cornerstone principles of respectful person-centered cancer care in which autonomous decision-making is maximally supported (Barry and Edgman-Levitan 2012). In the UK every person has the legal right to choose what happens to their body and to be adequately supported in sharing in the decision of whether to consent or reject any treatment

or care offered. The principle of informed consent has increasingly been recognized globally and UK law is clear that consent requires the person not only to understand what the proposed care involves including its risks and benefits and reasonable alternative options, but also for the process of decision-making to be a genuinely shared dialogue in which individual's values and preferences are addressed (Bernat and Peterson 2006). International case law is a testament to the global courts' increasing appreciation of patient autonomy over traditional paternalistic care. The Australian case of Rogers v Whitaker (1992) heralded the end of paternalistic, practitioner-oriented health care. UK law has increasingly endorsed the pre-eminence of patient-centric care and the importance of consultation dialogues which foster patient autonomy. In the landmark case of Montgomery v Lanarkshire Health Board (2015), which concerned the failure of an obstetrician to inform a woman of the risk of shoulder dystocia associated with vaginal delivery, the court stated that a doctor has a duty to ensure a patient is made aware of any *material* risks involved in treatment and of reasonable alternatives. What is *material* is determined both by reference to what a reasonable person in the patient's situation might want to know and what the *particular* patient would be likely to attach significance to according to their concerns, beliefs and values. Of interest to me across the articles in this volume is the adventitious exposure of the challenge inherent in this legal and professional requirement (General Medical Council 2020). Collectively, the articles reveal the complex interactional dynamics of choice and consent in cancer settings and the institutional practices and coping strategies, which although intended to facilitate a values and preferences based consent process, hold the potential to erase the presence of patients and staff alike and subsequently throw into question what it means to give or gain informed consent.

While there have been studies examining the understanding and quality of information provision among participants in clinical trials of cancer therapies (Joffe, et. al. 2001; Brown,

et. al. 2004), there is little empirical research specifically on patient or health practitioner experiences of the consent process in cancer care settings. Corrigan's (2003) qualitative interview study examined the process of consent as experienced by participants in clinical drug trials including two breast cancer trials. Decisions were made in social contexts involving a complex emotional nexus of professional, pragmatic and individual elements. Failure to embrace the context in which informed consent decisions are made, Corrigan argues, leads to an "empty ethics" of consent. Drawing on data with Brazilian families and individuals receiving genetic counselling for increased genetic risk of cancer, Goldim and Gibbon (2015) showed how informed consent is negotiated at the interface between the family and the individual. This work highlights the limitation of a consent process focused on information provision and a bioethics predominantly informed by the notion of autonomy. Consideration of solidarity between professionals, patients, family members or wider members of a community is advocated as a future approach to informed consent and is supported by developments in bioethics (Prainsack and Buyx 2017; Samuel, et. al. 2017).

As the articles in this special issue highlight, consent is not simply about acceptance of a suggested treatment but about choice between a range of options, including the option of declining treatment. To many people diagnosed with cancer, the notion of treatment choice and voluntariness is a chimera in the uncertain landscape of their illness. Patients consider their diagnosis robs them of any choice. As Greco (this issue) shows, a crisis of presence reduces patients' sense of agency for it is difficult for them to "foresee the possible evolution of their condition in the absence of certain knowledge". Fortin, et. al. (this issue) highlight the distress of a family who ask if they really have choices when without treatment their son will die. To remain on the side of life, all treatment that is offered must be borne whatever the cost to quality

of life and however small the potential benefit in terms of overall or progression free survival (Falchook, et. al. 2017).

The psycho-oncology literature provides many examples of patients' oscillation between knowing and not knowing the import of their diagnosis and for some, how close death may be, as they struggle with fluctuating health status, complicated treatment schedules, and unpredictable hospitalizations. This is an unsurprising response to the stark nature of cancer illness. Patients experience difficulties putting their understanding and meanings into words (Emanuel 2001), but a particular type of attention to these meanings may offer a profound comfort in the face of the illness and feed into a consent process in which the evasive medical responses noted by Greco in this issue translates to a thoughtful presence in the face of the trauma when patient and professional can together speak truth to the illness (Rodin, et. al. 2009). Health care professionals as well as patients vary in their reflective capacity and psychological mindedness in facing up to cancer (De Vries, et.al. 2014; Politi, et.al. 2011) and for those keen to think mostly positive thoughts, the uncertainty over new treatments can serve as an avoidant which becomes less tenable with progressive disease. As Fortin and colleagues show, health care professionals and families may emphasize hope and positive thinking, thereby silencing and dismissing the fears and concerns triggered by the cancer. How to manage these concerns and the decision-making consent process are complex tasks that may overwhelm health care professionals and confuse many patients so that concerns may not be addressed until it is too late in the course of illness for adequate attention (Step, et.al. 2009). In this scenario hope is predominantly considered in terms of action. Hope for the next treatment rather than hope based on what is satisfying and meaningful in a patient's life and a reconsideration of priorities and life goals for what may be a limited future or as Schoenfeld

denotes, “an indefinite and yet finite future” as a cancer survivor; a hope that widens to the family and friends who will survive them.

When a patient attends clinic to discuss a new cancer treatment with their doctor, the first questions are often “How will it make me feel?” and “How did other patients like me feel with this treatment?” The importance and utility of quality-of-life and patient reported outcome data in treatment decisions has been recognized by all sectors – patients, clinicians, funders, regulators, and policy-makers (Bottomley, et. al. 2016) Cancer patients have called for greater availability of these data alongside data giving insight into how long they may survive. Despite this, a recent systematic evaluation of patient reported outcome content and reporting in cancer trials noted that out of 160 trials that had published results by the time of the final publication search in June 2017, and with a mean of 6.43 year's follow-up from trial closure, more than one-third (38%) had failed to publish their patient reported outcome findings. Where these findings were published, there was often a significant delay (37% >4years) and reporting quality was poor. The randomized trials were all listed on the National Institute for Health Research (NIHR) Portfolio Database that included a PRO as either a primary or secondary outcome. The NIHR portfolio includes predominantly UK-led international and national trials, supported by a range of funders, adjudged as high-quality following peer review.

If consent to treatment is to be informed, patients need direct communication about the consequences of a treatment, what the side effects are, and how the treatment will impact not just their daily life but that of their family and those closest to them who may be needed to provide practical as well as emotional support. Where treatments are novel or delivered as part of early phase trials this information may not be available, but it is up to the oncology community to establish where the balance of benefit and harm lies with new treatments.

Patients, however, will ultimately bear the burden of interpretations of treatment trials, and thus should be asked to assess the inherent trade-offs implicated in new treatments. In this special issue the "treatment consequence" trade-offs of consent to standard protocol and novel treatments are laid bare. For example, in Arteaga's article, consent to treatment involves effortful fundraising to get the treatment in the first place followed by a legacy of chronic colitis. Greco describes the complexities of financially investing in a treatment which if successful would likely lead to insolvency. In Llewellyn's study, consent to a treatment choice distressingly precluded the option of another (better) treatment in the future, a decision which the patient and family considered was made without sufficiently being informed. It was an episode that affected the patient's relationship with the treating team and caused regret and sadness. Even in well-run cancer clinics, the fallibility of health care professionals, lapses in continuity of care, the speed of innovation in personalized treatments, and inevitable limitations in health care resources may be frustrating and distressing to patients and their families and compromise the consent process.

As the articles have eloquently described, fluctuations in patients' clinical condition, symptom control, and the receipt of prognostic news may drastically alter their capacity or motivation to contribute to decisions. Llewellyn refers to the urgency and time pressure to consent in an experimental high-stake treatment when there is minimal risk disclosure and a decision is made blind. For many patients, decisions regarding the initiation, continuation or cessation of medical treatments are distressing and difficult, particularly when first-line treatments have failed and in the context of "the myriad contingencies which foreclose, demand or steer patients' choices" (Llewellyn, this volume). While recent patient-centric medical care has many benefits, some may feel overwhelmed by participation in complex treatment decisions. They may not understand the information that they have received and therefore may have

difficulty making an informed decision (Smith, et. al. 2009). Treatment decisions may also be complicated by their own desperation, their own sense of being in-relation and part of a kin-network with an onus to be well (Hallowell 1999), or by perceived pressure from their family or from the treatment team. Since the meaning of the disease is determined at the intersections of various factors related to it, including the individual, social, and family situation, exploration of the range of thoughts and feelings that surface for a patient in relation to a treatment decision can help them to weigh their own thoughts and feelings, distinct from those they perceive in their health care providers, family, or friends. The process becomes in this case a process of relational consent in which the idea of the "autonomous subject" is an illusion forged by bioethics (Bell 2016).

Legal and professional guidance on patient consent sets a high bar for cancer health professionals working in an environment revolutionized by personalized medical science. The articles in this volume suggest that there is a mismatch between what is required of health care professionals to effect cancer treatment and care consent processes concordant with current legal and professional guidance and what can be achieved in practice. If consent, as currently articulated, is to remain the barometer for current practice, healthcare professionals need more support in ways of enabling patients to make decisions which healthcare professionals feel confident are autonomous whatever the circumstances of the consultation. However, there is a shift in bioethical thinking which acknowledges the importance not only of patient autonomy but solidarity and attentive commitment between a patient, their cancer treatment team and family members (Jennings et al 2018). There is also a shift in thinking within the cancer community and recognition that the consent process needs radical change (Perni et al 2021). What make the articles in this volume such a vital contribution to the cancer literature is how they point to the need for informed consent approaches that are relational and trusting, and in

which the consent process is necessarily one of continuous shared responsibility and deliberation.

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