

Words Matter: Distinguishing “Personalized Medicine” and “Biologically Personalized Therapeutics”

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“Personalized medicine” has become a generic term referring to techniques that evaluate either the host or the disease to enhance the likelihood of beneficial patient outcomes from treatment interventions. There is, however, much more to personalization of care than just identifying the biotherapeutic strategy with the highest likelihood of benefit. In its new meaning, “personalized medicine” could overshadow the individually tailored, whole-person care that is at the bedrock of what people need and want when they are ill. Since names and definitional terms set the scope of the discourse, they have the power to define what personalized medicine includes or does not include, thus influencing the scope of the professional purview regarding the delivery of personalized care. Taxonomic accuracy is important in understanding the differences between therapeutic interventions that are distinguishable in their aims, indications, scope, benefits, and risks. In order to restore the due emphasis to the patient and his or her needs, we assert that it is necessary, albeit belated, to deconflate the contemporary term “personalized medicine” by taxonomizing this therapeutic strategy more accurately as “biologically personalized therapeutics” (BPT). The scope of truly personalized medicine and its relationship to biologically personalized therapeutics is described, emphasizing that the best of care must give due recognition and emphasis to both BPT and truly personalized medicine.

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Words matter. Concepts matter. Words guide us, constrain us, and help us. Concepts shape our perceptions and our imagination. An emerging concept in medicine has arrived, with its new name, new technologies, and a bright new future. But it should not be allowed to eclipse a concept of medical care that shares its name. “Personalized medicine” in its new meaning could overshadow the individually tailored, whole-person care that is at the bedrock of what people need and want when they are ill.

Without undermining the needs and potential of the new area, we wish to keep the terminology of medicine suited to the needs of patients. The era of “personalized medicine” in its new meaning seems to herald a new epoch in the care of cancer patients. Rather than having medications recommended on the basis of diagnosis and staging, “personalized medicine” suggests that tailored treatments based on assessment of biological parameters of the individual or the underlying disease can improve patient outcomes by identifying those patients most likely to benefit from specific therapies and, simultaneously, diminishing the use of medications for patients who can be predicted not to derive benefit from them (1,2). Consequently, it may reduce costs and the risk of adverse effects from ineffectual treatments, and it may prevent delays in employing alternative therapeutic options with a higher likelihood of benefit. We welcome this development.

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interventions (3). Approaches evaluating the individual patient/host include evaluation of germline polymorphisms and pharmacogenomics to better select drugs and avoid toxicity (4,5). Techniques evaluating the disease include strategies to target specific identifiable molecular targets (targeted therapy) (6–8), genomic analysis for positive or negative predictive indicators for specific therapeutic options (9–12), scanning with radiolabeled ligand probes for specific receptors (13), individualized drug selection based on sophisticated in vivo drug testing of individual patient tumor clones, for example, grown in mice avatars (14,15) or through the identification of rare altered molecules in bodily fluids to monitor disease burden and response to treatment (16). Again, we welcome the development but not the name it has chosen to purloin.

In its current incarnation, the term first appeared in the recent medical literature in the late 1990s (17,18). However, truly targeted therapy directed at the estrogen receptor in breast cancer had been introduced decades earlier. “Personalized medicine” is also sometimes called pharmacogenomics (19), theragnostics or theranostics (20), personalized molecular medicine (21), clinical proteomics (21) or individualized targeted therapy (22), stratified medicine (23), and precision medicine (24,25). Despite this burgeoning nomenclature, the term “personalized medicine” has predominated (26) and is incorporated into the title of no fewer than six medical journals (Table 1) and into the titles of dedicated sessions in major cancer conferences. Although “personalized medicine” has been largely developed for cancer care, it is also a developing area of interest in

Table 1. Medical journals with “personalized medicine” in titles

<i>Personalized Medicine Universe</i>
<i>Current Pharmacogenomics And Personalized Medicine</i>
<i>Journal Of Functional Informatics And Personalized Medicine</i>
<i>Journal Of Personalized Medicine</i>
<i>Personalized Medicine</i>
<i>Personalized Medicine In Oncology</i>

neurology (27–29), psychiatry (29,30), cardiology (31–33), pulmonology (34), rheumatology (35,36), endocrinology (37), and ophthalmology (38).

There is, however, much more to personalization of care than just identifying the biotherapeutic strategy with the highest likelihood of benefit. The lived experience of cancer is complex, and this is reflected in the tailored care needs of all persons’ suffering in all its dimensions, biological and beyond (39–44). Skilled cancer care, especially of those with advanced cancer, requires an approach that is cognizant of these diverse, personally specific needs. This underscores the necessity for oncologists to develop an understanding and sensitivity to the broad scope of patient care needs, as is recognized by names of cancer centers that include terms such as “comprehensive cancer care.”

These needs include tumor control and symptom management in general, and a detailed understanding of the specific care needs, concerns, and potential complicating factors in each individual patient’s circumstances. These circumstances vary with patients’ values, cultural backgrounds, social circumstances, and/or psychological well being. The quality of the therapeutic relationship between the patient and/or family and the health care providers requires that professionals are honest, sensitive, respectful, patient, and accessible. The professional team must use these skills to understand and respond to the myriad possible ways in which patients and families cope as they deal with uncertainty and fear, sadness and/or anger, supporting them as they maintain a sense of control, find meaning, handle the emotional distress of others, and navigate their changes in self-perception (physical, family, social, sexual).

The critical importance of these issues is underscored by studies conducted to determine the content of areas for the development of tools to evaluate the needs of patients with advanced cancer (45,46) and the severity and causes of patient distress that Saunders called ‘total pain’ (47). These emphasize the importance of multiple domains, including: medical communication and information giving, psychological and emotional well being, activities of daily living, financial concerns, symptom control, spiritual concerns, and social supports and functioning (48).

This approach to personalization was highlighted by the American Society of Clinical Oncology (ASCO) in an important statement “Toward Individualized Care for Patients With Advanced Cancer” (49). This special paper outlined the issues in personalizing care, the need for careful patient evaluation and nuanced counseling regarding treatment options, careful follow-up, and the early introduction of integrated palliative and supportive care. In its original use, dating back to the 1940s, the recently coined term “personalized medicine,” refers to a whole-person approach to care (50). In contrast, the term “individualized medicine” has a more limited history, and in the three years since the ASCO Statement

(49) it has received little or no attention. Indeed, in recent literature it is used interchangeably with “personalized medicine” in referring to biologically targeted therapies (22), further edging out the major bedrock concept of whole-person, tailored care.

In addition to the fact that the contemporary use of the term “personalized medicine” is too narrow, at the expense of the critical concept it used to refer to, the field sometimes exudes an overconfidence in its deliverables, which have actually been variable (some outcomes have been dramatic, others minor or inconsequential) (51,52). Furthermore, the term is sometimes used as a marketing strategy for institutions, investigations, and new medical technologies that could falsely appeal to an expectation of whole-person care.

If the term is not respectfully limited to its intent, it will have to account for potential harm insofar as its bioscience emphasis implicitly diminishes the scope of what constitutes personal medical care and the biopsychosocial complexity of personhood. This claim is supported by the observation that considerations of the individual, needs and/or distress assessment, and of all of the complex aspects of providing a comprehensive care plan are glaringly absent in the chapters, journals, reviews, and meetings dedicated to the new concept now denoted by the term “personalized medicine.” Indeed, the literature devoted to personalized medicine is characterized by a striking paucity of attention to the patient communication and decision-making issues associated with the proposal of these approaches. This shortcoming is particularly salient when considering the application of such approaches in the advanced stages of disease when disease-modifying options may be limited, quality of life and symptom burden are substantial, and life expectancy is short.

This bioscience culture of care characterized by the contemporary understanding of “personalized medicine” has not gone unnoticed by patients and patient advocacy groups. It is not that they do not want the benefits of the new technologies and the fruits of the rapid advances in the understanding of disease biology; they do and rightly so. However, they also want to be seen and treated as more than the biology of their diseases (42,44,53–58), and we want this for them too. Along with the new therapeutic approaches, they want a commitment of care that is sensitive to their complex and often changing needs as they confront the ravages of illness and the vicissitudes of treatments undertaken, in trust, with the hope of benefit and in fear of harm. They want physicians who are confident, empathetic, humane, personal, forthright, respectful, and thorough (59). These standards are mandated by credentialing bodies and increasingly addressed in medical school training programs (60–63) and have received strong endorsement in the oncology literature addressing principles of professionalism (51,64,65) and the incorporation of psychosocial issues as a core element of cancer care (66,67).

Finally, names and definitional terms are not just a matter of fussy semantics. They set the scope of the discourse (68) and have the power to define what personalized medicine includes or does not include, thus influencing the scope of the professional purview regarding the delivery of personalized care. Medicine is more than just the administration of therapeutic interventions; it incorporates pharmacological and biological therapeutics as part of a complex interpersonal intervention that constitutes medical care (69–73).

Taxonomic accuracy, understood to be critical for diagnoses, is no less important in understanding the therapeutic interventions that are distinguishable in their aims, indications, scope, benefits, and risks. In order to restore the due emphasis to the patient and their needs, we assert that it is necessary, albeit belated, to deconflate the contemporary term “personalized medicine” by taxonomizing this therapeutic strategy more accurately as “biologically personalized therapeutics” (BPT). BPT should be a part of true personalized medicine (Figure 1), but it is far from being the embodiment of it.

Table 2 sets out areas of the biopsychosocial model of medicine that must be as personalized as the genetically informed biological care. Each person has individual needs for communication, for psychological and emotional well being, social functioning, and spiritual expression and care; in very few cases would the exact same approach work for all people with a similar condition. Moreover, for each domain, there is no substitute for getting to know the person and how he or she works; without this step, an appropriate tailored approach to care is impossible. This is illustrated by considering the relative gravity of these considerations in the care of a 73-year-old woman with metastatic melanoma (Table 3).

This return conceptualization of personalized medicine restores due emphasis to biopsychosocial care by including communication and information giving, psychological and emotional well being, enhancing function, addressing financial concerns, symptom control, spiritual concerns, and social supports.

Table 2. The purview of personalized medicine

Psycho social evaluation	Communication and information giving preferences Psychological and emotional well being Financial concerns Spiritual concerns Social supports Goals of care Fears and concern Hopes and ambitions
Disease evaluation	Accurate diagnosis Relevant biological evaluation of host and disease Symptom evaluation Functional evaluation
Therapeutic Personalization	Agreed and relevant goals of care Effective supportive communication Evaluation of therapeutic options and preferences Disease and stage appropriate therapeutics Biologically personalized therapeutics Symptom management Supportive care Psychological Functional enhancement Support strategies: social, financial Spiritual
Longitudinal care	Reevaluation Therapeutic adjustments

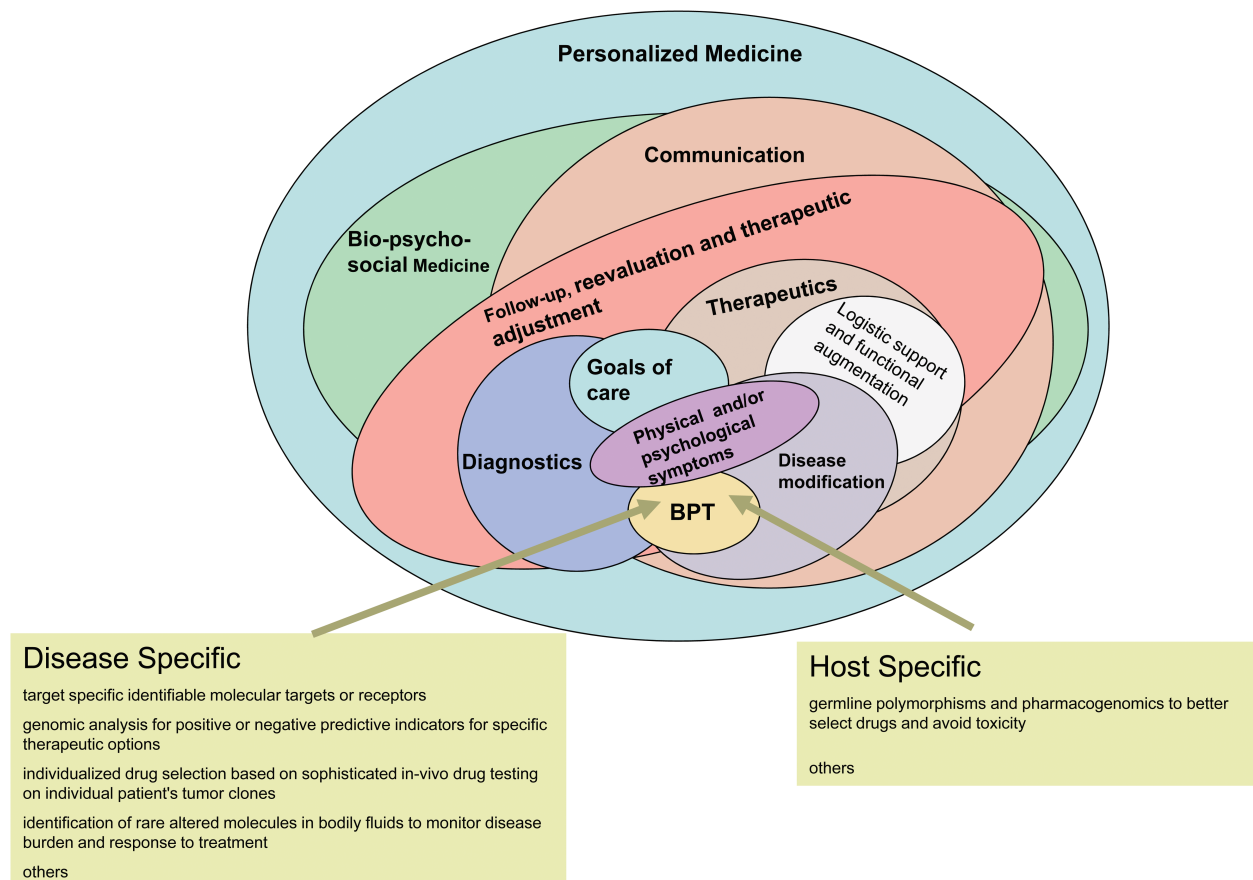


Figure 1. The relationship between personalized medicine and biologically personalized therapeutics (BPT).

Table 3. A case for consideration: personalizing the care of a 73-year-old woman with metastatic melanoma

Biologic personalized therapeutics

Mrs. M is a 73-year-old woman with metastatic melanoma with multiple pleural masses and genomics revealing an actionable B-RAF V600E mutation indicating that the disease is amenable to treatment with vemurafenib.

Other dimensions of personalizing medical care

Mrs. M is a 73-year old-widow who lives alone in a third-floor walk-up apartment. She has metastatic melanoma with multiple pleural masses that are complicated by moderate to severe chronic pain and dyspnea on exertion. Controlled release morphine tablets are providing only partial and inadequate relief of her pain, and she is distressed by constipation. She has a daughter who is able to help her on weekends. She is anxious about her future and fearful about the prospects of severe pain or suffocation at the end of life. She is aware that her disease is incurable and that her anticipated life expectancy is limited. She is interested in life-prolonging treatment but only if it has minimal risk of side effects. She is a pensioner with limited financial resources and her insurance has a 25% copayment on medications.

Indeed, the best of care must give due recognition and emphasis to both “biologically personalized therapeutics” (BPT) and truly personalized medicine.

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Notes

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