



Feature Article

Surviving with lung cancer: Medication-taking and oral targeted therapy

Karen E. Wickersham, PhD, RN^{a,d,*}, Mary Beth Happ, PhD, RN, FAAN^{a,c},
Catherine M. Bender, PhD, RN, FAAN^a, Sandra J. Engberg, PhD, CRNP, RN, FAAN^a,
Ahmad Tarhini, MD, PhD, MSc^b, Judith A. Erlen, PhD, RN, FAAN^a

^a University of Pittsburgh School of Nursing, USA

^b University of Pittsburgh School of Medicine, USA

^c The Ohio State University College of Nursing, USA

^d University of Maryland, Baltimore, School of Nursing, USA

A B S T R A C T

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Oral epidermal growth factor receptor inhibitors (EGFRIs) improve survival for non-small cell lung cancer (NSCLC) patients; however, medication-taking implications are unknown. We used grounded theory to explore the process of medication-taking for NSCLC patients receiving oral EGFRIs. Thirty-two interviews were conducted for 13 participants purposively selected for gender, race/ethnicity, age, time in therapy, dose reductions, and therapy discontinuation and theoretically sampled for age and health insurance carrier. The study produced a grounded theory, *Surviving with Lung Cancer*, in which participants framed EGFRi therapy within recognition of NSCLC as a life-limiting illness without cure. Medication-taking was a “window” into participants’ process of surviving with metastatic cancer that included *deciding* and *preparing* to take EGFRIs and *treating* lung cancer as a chronic condition. Our results contribute to understanding how NSCLC patients view themselves in the context of a life-limiting illness and support development of a theoretically-based intervention to improve medication-taking with EGFRIs.

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Introduction

Lung cancer is the leading cause of cancer deaths in the US for both men and women, with 159,480 deaths estimated for 2013.¹ Non-small cell lung cancer (NSCLC) comprises approximately 85% of lung cancer cases and occurs in both smokers and nonsmokers.² NSCLC adenocarcinoma is largely a disease of older adults.^{3–6} The mean age at diagnosis is 71 years of age. Lung cancer represents a major disease burden in older adults⁷; overall, approximately 70% of patients with NSCLC are diagnosed at an advanced stage (stage III/IV), are over 65 years of age at the time of diagnosis, and have a 15.6% five-year relative survival rate.^{1,5}

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* Corresponding author. University of Maryland, Baltimore, School of Nursing, RM 731A, 655 West Lombard Street, Baltimore, MD 21201, USA. Tel.: +1 410 706 5119.

E-mail address: wickersham@son.umaryland.edu (K.E. Wickersham).

The approach to NSCLC treatment has shifted to increased use of oral targeted therapies.⁸ For NSCLC patients, targeted therapy development has focused on the epidermal growth factor receptor (EGFR). Oral EGFR inhibitors (EGFRIs), such as erlotinib (Tarceva[®], OSI Pharmaceuticals, Farmingdale, NY), play a key role in management of advanced stage NSCLC. Generally, oral EGFRIs for advanced NSCLC are taken daily until they become ineffective (weeks to years), unlike oral chemotherapy (e.g., capecitabine) or hormonal therapy (e.g., anastrozole). Medication-taking of oral EGFRIs, which includes activities such as identifying and counting pills, timing pill taking with meals, and refilling prescriptions,⁹ is crucial for prolonging survival for persons with NSCLC; however, individuals aged 70 years and older face unique challenges that may influence medication-taking behaviors related to oral EGFRi therapy, such as negotiating the effects of multiple co-morbidities,^{10–12} managing complicated medication regimens,¹³ suffering from functional and cognitive declines and experiencing depressive symptomatology.^{14,15} Unfortunately, there is little research to guide our understanding of the medication-taking process or the meaning of medication-taking for adults receiving oral EGFRi therapy. Therefore, the purpose of this grounded theory study was to explore the process of medication-taking for adults with NSCLC taking oral EGFRIs.

Traditionally, NSCLC has been treated with surgery, chemotherapy, and/or radiation therapy (Table 1); however, recent advances in understanding genetic mutations in cancer¹⁶ have led to development of new drugs to target these mutations and improve survival. For persons with NSCLC, tyrosine kinase inhibitors that disrupt function of the EGFR improve survival and quality of life.^{17,18} The oral EGFRi approved for use for NSCLC treatment at the time we conducted our study was erlotinib, which is now approved for: (1) first-line therapy for patients with metastatic NSCLC with EGFR exon 19 deletions or exon 21 (L858R) substitution mutations^{19,20}; (2) treatment of refractory NSCLC (2nd, 3rd line therapy) of non-squamous and squamous histology,¹⁸ where it is most widely used; and (3) maintenance therapy after 1st line platinum-based chemotherapy in persons who achieve stable disease or response.²¹

Medication-taking and erlotinib

Erlotinib is less toxic and more convenient for patients to take compared to standard chemotherapy; however, the side effect profile of erlotinib is unique to the pathway it inhibits. Common side effects of erlotinib include rash, diarrhea, fatigue, and anorexia.²² The effect of the experience of medication-taking with erlotinib, including impact of side effects on medication-taking behaviors, for persons with NSCLC is not understood. Qualitative inquiry provides unique information about medication-taking behaviors and experiences of patients with chronic disorders.^{23–26} Most qualitative studies of medication-taking of patients with cancer are focused on developmental issues such as egocentrism, concrete thinking, and parental involvement among children or adolescents.^{25,27} Understanding the process of medication-taking for adults with NSCLC taking oral EGFRi therapy is necessary to provide comprehensive patient-centered care and to develop and test interventions tailored to the needs of persons with NSCLC.

The study

Aim

We explored the process of medication-taking for adults with NSCLC receiving oral EGFRi therapy. Our goal was to develop a

Table 1
Treatment of non-small cell lung cancer by stage of disease.

TNM stage	Treatment
Occult carcinoma	Observation
0	Observation
IA	If operable, surgical resection ± observation/SABR
IB	If operable, surgical resection ± observation/SABR/chemotherapy
IIA	If operable, surgical resection ± observation/SABR/chemotherapy/chemoradiation
IIB	If operable, surgical resection ± observation/SABR/chemotherapy/chemoradiation
IIIA	Chemotherapy or concurrent chemoradiation
IIIB	Concurrent chemoradiation
IV	If mutation + = erlotinib, afatanib (EGFR+) or crizotinib (EML4 rearrangement +) If mutation – and PS 0–1 = <ul style="list-style-type: none"> • Doublet chemotherapy • Chemotherapy + bevacizumab • Cisplatin/pemetrexed • Cetuximab/vinorelbine/pemetrexed If mutation – and PS 2 = chemotherapy If mutation – and PS 3 = best supportive care

SABR = stereotactic ablative radiotherapy; T = primary tumor; N = regional lymph node involvement; M = metastases; PS = performance status; EGFR = epidermal growth factor receptor; EML4 = echinoderm microtubule-associated protein-like 4. Adapted from Lababede et al (2011).

grounded theory that described and explained the process of medication-taking for adults in this patient population.

Design

We used grounded theory for the purpose of constructing, testing, and refining theory from data.^{28,29} The underlying assumption of grounded theory is that groups of individuals share a distinct psychosocial problem that is resolved through a process.²⁸

Setting and sample

Our university Institutional Review Board approved this study. Informed consent was obtained from all participants prior to data collection. Participants were individuals treated for NSCLC at two outpatient lung cancer clinics at a National Cancer Institute-designated cancer center. The principal investigator (PI; KW) was not part of the clinical care team and used clinic observations and chart reviews to screen eligible patients and to understand the participant's treatment trajectory. Members of the clinical team (i.e., an oncologist, a nurse practitioner, physician's assistant, or a collaborative nurse) identified and approached potential participants to assess their interest in study participation. The PI met with interested patients in a private area at the recruitment sites or discussed the study by phone.

Participants

Men and women over 21 years of age with NSCLC (any type/stage) receiving an oral EGFRi and able to speak, read, and understand English were eligible for the study. Exclusion criteria included a primary cancer that had metastasized to the lung or a second primary cancer, current metastasis to the central nervous system, or evidence of cognitive impairment as assessed by Mini-Mental Status Exam (MMSE)³⁰ scores at or below the borderline range (1.4 SD below age- and education-scaled norm).³¹

Participants were purposively selected for variation in gender, race/ethnicity, age, time in therapy, reductions in dose of their EGFRi, and therapy discontinuation.³² Twenty patients expressed interest in the study; one was excluded for a second primary cancer and six did not enroll (e.g., “too much going on,” disclosure concerns, declining performance status). None were excluded due to cognitive dysfunction.

Data collection: interviews

Data were collected from August 2011 to August 2012. The PI conducted digitally recorded, in-depth, semi-formal interviews ($n = 27$) with 13 participants and five brief telephone interviews for follow-up using an interview guide with questions about EGFRi medication-taking behaviors (Table 2).^{24,33,34} Interviews ranged from 32 to 90 min and were conducted in the participant's home or at a convenient location that afforded privacy for the participant. Most ($n = 10$) were interviewed on multiple occasions to capture the medication-taking process in early, middle, and later phases of erlotinib use. The (two) recorders failed for one interview, which was reconstructed immediately. Participants received \$10 after each interview.

As data collection and analysis progressed, we added questions about treatment delays, support groups for persons receiving oral EGFRi, prescription medication insurance coverage, and disclosure of NSCLC and/or EGFRi use to family or friends. Supplemental data sources included an erlotinib starter kit, lay cancer journals, prescription package inserts, and personal documents (e.g., transcript of a speech) given to the PI by the participants or the clinical team.

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