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Abstract

This paper presents a discussion on both positive and negative influences on quality of prescribing in clinical practice. It explores how such influences impact on breast cancer patients on adjuvant hormonal therapy. Nurse prescribing is a relatively new development within nursing in Ireland and continues to develop. Guiding the registered prescribing nurse in practice, prescribing duties are undertaken in line with a dual framework incorporating both legislative and professional mandates. Though these guidelines serve to direct and ensure quality prescribing, no governing mandate meets all the complexities and challenges faced in clinical practice. This paper critically analyses how differing factors impact on the process of quality prescribing for breast cancer patients on adjuvant hormonal therapy. Factors explored include the prescriber, patient, illness, also the healthcare setting and economics. Since hormonal therapy in the adjuvant setting for breast cancer patients is associated with a reduction in both recurrence and mortality rates. The impact of quality prescribing can result in a meaningful long term outcome for this particular group of patients.

Introduction: Medication management is regarded as a highly complex process (Brady et al, 2009). It requires the correct completion of four phases which include prescription,

transcription, dispensing, and administration of a drug in order to avoid potential medication administrative errors (MAEs) (McBride-Henry and Foureur, 2005).

Whilst prescribing itself is the single most common occurring intervention within health care (Culley, 2010), nurses having prescriptive authority is a relatively new development particularly in the last 20 years (Kroezyn et al, 2011). Originating in the United States in 1969 (O`Malley, 2014), nurses holding prescriptive authority now include a total of seven countries of which include Britain (1998) and most recently Ireland (2007) (Naughton et al, 2013). However, relevant legislation and professional scope of practices pertaining to nurses with prescriptive authority are distinctly different between countries; for instance, both Britain and Ireland have broader independent prescribing rights than evident in other jurisdictions (Kroezyn et al, 2011). A recent systematic review by Creedon et al, (2014) found that internationally regardless of such jurisdictional differences, nurse prescribing introduction has led to an improvement in the quality of care for patients

In order to safeguard patients and ensure quality prescribing, the registered nurse holding prescriptive authority in Ireland has a responsibility to fulfil prescribing duties in line with a dual framework that incorporates both legislative and professional requirements (An Bord Altranais, (ABA) 2010) (the governing board for nursing in Ireland now formally known as the Nursing and Midwifery Board of Ireland (NMBI)).

This paper critically analyses factors that impact on quality prescribing (QP) with a focus on breast cancer patients on adjuvant hormonal therapy. How such factors can influence the nurse prescribing process and its associated outcome in both a positive and negative way. The paper specifically explores how such issues relate to breast cancer patients on hormonal therapy follow up. Protocol mandated long term follow up is commonly associated with the enrolled breast cancer patient in the randomised control trial (Winter et al, 2011). Recent

guideline updates from the American Society of Clinical Oncology (ASCO), recommend adjuvant hormonal therapy for all breast cancer patients with ER positive disease, and depending on category of risk, age, menopausal status, the duration of therapy may range between five to ten years (Burstein, 2016).

Prescriber: Positive Influences on QP: In terms of accountability and competency, nurse prescribing in Ireland is guided by the scope of nursing practice (NMBI, 2015) and code of professional conduct (NMBI 2014). Additional guidance is provided by the practice standards and guidelines for nurses and midwives with prescriptive authority (ABA, 2010) and guidance to nurses and midwives on medication management (ABA, 2007). Understanding and knowledge of relevant legislation and legal implications of practice as laid out in Medicinal Products (*Prescription and Control of Supply*) Regulations 2007 (S.I. No. 201 of 2007)(Government of Ireland (GOI), 2007), and Misuse of drug (*Amendment*) Regulations 2007(S.I. No. 200 of 2007) (GOI, 2007). An essential component of nurse prescribing registration is an agreed robust collaborative practice agreement (CPA) (ABA, 2012), a document which requires the nurse's local Drugs and Therapeutics committee's approval, restricts and specifies the list of medications that the nurse can prescribe, and as such it forms the contract between the nurse prescriber (NP), medical consultant and the local health service (Naughton et al, 2013). The NP should also implement the underlying principles of prescribing during each patient consultation, i.e. the 5 rights of medication administration mainly the right drug, patient, dose, form and time (ABA, 2007).

The quality measures described above represent both professional and legislation mandates of clinical practice, however the clinical impact attested from patients' experience of NP consultations, is evident in the fundamental core nursing qualities employed by the prescribing nurses. Nursing is derived from a profession of caring and is patient centred in approach (NMBI, 2014), and patients report that the comprehensive nurse consultation

process (Drennan et al, 2009), and extensive level of information and education given by the NP to the patient (Jones et al, 2011) are positive prescribing qualities. High value is placed on the NP's caring holistic approach which ultimately transpires towards prescribing within the context of the individual patient's life (Bradley and Nolan, 2007). In Ireland prior to the introduction of the prescribing nurse national initiative, these positive NP attributes found in other jurisdictions, such as increased rate of medication concordance, convenience and accessibility for patients as well as appropriate decision making by NPs as supportive evidence for identifying the need for the Nurse/Midwife Prescribing development here nationally (ABA, 2005).

Prescriber: Negative influences on QP: Despite stringent professional guidelines and legislative mandates which direct the NP and ensure quality in clinical practice, the prevention of MAEs in healthcare is an ongoing challenge encountered daily in practice (Brady et al, 2009). Of integral value is the importance of the therapeutic relationship between the prescriber and the patient, wherein a prescriber advocates and recognises the patient in terms of equal partnership in medication management (Latter et al, 2007). Ineffective therapeutic relationships demonstrated among medical professionals are attributed with decreased rates of medication adherence in patients (Osterberg and Blaschke, 2005). In the case of breast cancer patients on adjuvant and prevention hormonal therapy, a recent literature review identified the challenge caused by in-effective communication between the patient and physician, where the patient does not feel enabled to discuss beliefs and expectations regarding continual hormonal therapy and the prescriber does not effectively communicate regarding the significance and importance of adherence with that therapy (Chlebowski et al, 2014). This is of great significance given the clinical outcome for the adjuvant breast cancer patient is that appropriate therapy and duration of treatment with hormonal therapy is associated with a reduction in recurrence risk, reduction in development

of metastasis and a decrease in morbidity rates (Early Breast Cancer Trialists Collaborative Group, 2005) (EBCTCG). The NP may benefit in learning from our medical colleagues by avoiding these issues as described above as well as some common documented prescribing errors such as illegible handwriting, inappropriate dosing and poorly informed consent processes, which may significantly contribute towards MAEs (Benjamin, 2003).

Combination of Prescriber/Healthcare Settings that negatively influence QP:

Demonstrating that influencing factors do not occur in isolation, the literature shows how differing combinations of healthcare settings and specialty of prescriber can negatively influence QP. These include a lack of knowledge reported among mental health prescribers (Snowden and Martin, 2010), training not specific to cancer as reported by Macmillan NPs in the UK (Ryan-Woolley et al, 2007) and limited knowledge regarding drug interactions in nursing homes as in polypharmacy (Dilles et al, 2011). Workload is regularly highlighted internationally as having a negative impact on quality of prescribing (O'Malley, 2014; Agboji, 2012). This may be attributed to a busy ward environment or colleague interruptions during the actual prescribing process leading to potential MAEs (Dilles et al, 2011).

Patient: Positive Influences on QP: Prescribing is challenging in terms of being complex and diverse with factors both “within” and “external” to the patient influencing the quality of the prescribing process. Jin’s (2008) systematic review identified external factors such as the healthcare system, social/economic factors, internal factors included therapy-related, disease and patient centred as associated with poor therapeutic compliance. A retrospective study on breast cancer patients adherence with hormonal therapy, found that those who were higher educated, held economic stability, had a strong network of support that included both the family and the multi-professional team, were more adherent with therapy (Brito et al, 2014). The NP managing breast cancer patients should be cognisant of patient characteristics that can potentially influence toward positive/negative therapeutic outcome during the prescribing

process. The importance is when establishing concordance with the individual patient within a joint decision making process, the NP should endeavour to recognise the individual patient and their diverse unique needs as central. Therefore by identifying not only the patient qualities but also vulnerabilities, the NP may promote not only quality prescribing but concordance with therapy.

Patient: Negative Influences on QP: The physical effects of ageing, such as hearing difficulty and speech impairment and cognitive dysfunctions such as forgetfulness and the onset of dementia, can make history taking during patient consultations challenging (Fisher, 2016). The challenge associated with the confused and possibly frightened patient admitted to hospital also affects the quality of consultations (Teodorczuk et al, 2013). Fisher (2016) concludes however that the use of the term “poor historian” should cease and emphasises the importance of training new doctors in ways that they themselves become the historians for the patient. This suggestion illustrates that the focus should shift from the ‘challenging’ type of patient to the doctor’s approach in effectively meeting such challenges.

Specific to adjuvant breast cancer patients that continue on hormonal therapy, negative influences on QP include a lack of understanding in terms of significance of continual therapy (Verma et al, 2011). In addition the unwanted side effects associated with therapy such as hot flushes, decreased libido and an increase in weight (Ziller et al, 2009) have all been associated with non-concordance. Since continuing on hormonal therapy in adjuvant breast cancer ER positive disease as demonstrated in clinical trials may effectively half the rates of breast disease mortality during the second decade after diagnosis (Davies et al, 2013). Therefore the NP in fulfilling her role should ensure that each patient has understood the clinical significance in order to ensure the best possible long term clinical outcome.

Healthcare setting: Positive influences on QP: Generic measures within acute services include factors such as good collaborative workings between relevant stakeholders, communication and effective MDTs resulting in decreased rates of MAEs (Naughton et al, 2013). In a recent review of Scottish NPs, clinical supervision and auditing were also recognised as being central toward ensuring ongoing quality NP (Coull et al, 2013) and cancer nurses reported the importance of continual mentorship post training as an important mechanism of support in their prescribing practice (Ryan-Woolley et al, 2007).

Positive influence of Clinical Research Setting on QP: In breast cancer clinical trials, noted outcomes include higher rates of adherence with hormonal therapy compared with breast cancer patients in standard practice (Chlebowski et al, 2014 Verma et al, 2011). Facilitating this positive outcome within a trial setting includes the additional protocol mandated visits and assessments resulting in more frequent patient contact and directed concern regarding ongoing hormonal therapy maintenance (Chlebowski et al, 2014). One review identified a number of measures that both prescriber/patient can utilise to measure and improve medication adherence in clinical trials, these included direct observation of medicating (only applicable within the acute clinical setting), self- reporting, utilising diaries or electronic systems, pill counts, drug assays, electronic monitoring such as the electronic recording system MEMS in Switzerland (Matsui 2009). Apart from these practical approaches, factors “within patients” enrolled in clinical trials are associated with feeling better treated and educated regarding their treatment/disease, therefore more knowledgeable and as a result of being better informed there is an associated positive psychological benefit (Drennan 2002). This suggests that the clinical trial setting itself is associated with quality prescribing.

Healthcare setting/ Economic: Negative influences on QP: As highlighted above, prescriber measures (different healthcare settings) can pose unique challenges in the prescribing process. The healthcare setting is not just limited to the actual prescribing

environment, but also reflects the supports in place that enables the NP to effectively perform his/her prescribing duties. One healthcare support specific to the NP process is how data on prescribing activities is collected. However, the current National dataset system in Ireland (the Minimum Data Set (MDS) (Adams et al, 2010) has been criticised (Creedon et al, 2014). A recent review by Irish NPs has identified that the MDS system is constraining in terms of time and workload because it requires the inputting of prescribing data at the time of prescribing, and some nurse prescribers admit to avoiding prescribing due to more urgent clinical demands (Creedon et al, 2014).

This contrasts with the original aim of electronic systems in healthcare which includes decreasing paperwork, prescriber workload, a quality initiative which would be cost effective (Jamal et al, 2009). These issues with electronic systems have also been a challenge in the US, where the maintenance of patients' records and drug therapies have been reported as time consuming, and therefore are often not maintained up to date, with important patient data potentially been incomplete (Ljunberg et al, 2010).

Economic: Positive influences on QP: Recent projections in incidence of breast cancer in Ireland estimate an increase of 125% between the years of 2010-2040 (National Cancer Control Program, 2014). Such figures should continue to urge state economic investment, but also highlight to both professional nursing and educational bodies the need for continual effort in the support/ education and expansion of the role of nurse prescribing within oncology as a matter of urgency. A recent economic analysis undertaken in the UK highlighted that the economic measure in terms of investing in non-medical prescribing (NMP) has resulted in close to an estimated cost savings of £800million annually (Health IS, 2015). Outcomes used to estimate these savings included a reduction in visits to G.Ps, reduction in hospitalisations, facilitated through the contact with patients and nurse prescribers within the North West region of the UK (Merrifield, 2015). This example

illustrates the economic benefit in educating and promoting NPs, thereby managing patients within the primary care setting and reducing costs associated with G.P visits or hospitalisations (Health I5 2015).

Economic: Negative influences on QP: In Ireland, recent national economic challenges, government policies which included a moratorium placed on staff recruitment (HSE 2009), and an incentivised early retirement scheme for public service workers (Department of Finance 2009) has had a negative impact on the overall quality of healthcare. This has resulted in a substantial decrease in the number of experienced nursing staff in clinical practice and an associated increase in workload for those remaining. Before the onset of these economic challenges outcomes such as workload, lack of support/resources in clinical settings were all highlighted as potential barriers to implementation of NP (Lockwood and Fealy, 2008). Nevertheless, despite such challenges, a recent evaluative study indicates that the introduction of NP has as in other jurisdictions, demonstrated safe and appropriate decision making (Naughton et al, 2013).

Illness: Positive and Negative influences on QP: It is argued that illness is an elusive concept, i.e. the personal nature of the illness within the individual (Boyd, 2000). This view raises interesting questions on illness relative to the prescribing process, such as the notion of timing relative to illness, and whether a disease is acute versus chronic. For instance, the acute stage of a cancer diagnosis, may present as a serious life threatening diagnosis for the patient therefore patients are more adherent with therapy (Verma et al, 2011). However, this acute stage in any disease trajectory is associated with higher rates of medication compliance (Osterberg and Blaschke, 2005). Having a history of illness such as familial cancer also positively influences therapeutic concordance (Simon et al, 2014). On the other hand patients with chronic conditions are challenging (Ziller et al, 2009) with conditions such as hypercholesterolemia and hypertension being associated with medication nonadherence

(Kripalani et al, 2007). This is compounded among breast cancer patients where beliefs and perceptions in terms of benefit of therapy (Chelbowski et al, 2014) due to the absence of physical symptoms and a perception that therapy is indeed no longer necessary (Verma et al, 2011), may result in decreased adherence over time.

Conclusion: Both professional and legislative nursing guidelines govern and direct quality prescribing, however such mandates do not address all the complexities and challenges that are met in clinical practice. A variety of factors, such as prescriber, patient, illness, healthcare setting and economics can bring both positive and negative influences on the quality of prescribing.

In the oncology setting in prescribing for women with breast cancer on adjuvant hormonal therapy, the NP should endeavour to impart to each individual patient, knowledge regarding their disease and potential disease pathway in order to achieve concordance. Through nurturing each patients belief and trust through positive patient-prescriber communication, facilitates patient joint involvement in appropriate decision making.

Since adjuvant hormonal therapy is associated with a reduction in both breast cancer rates of recurrence and mortality rates (EBCTCG, 2005). NP in effectively meeting any challenging factors within clinical practice for this particular patient population ultimately promotes QP, and the long term clinical outcomes for patients on adjuvant hormonal therapy.

Key Phrases:

- .Quality nurse prescribing is undertaken in line with a dual framework that incorporates both legislative and professional requirements.
- Factors affecting quality of prescribing are not just limited to the patient, prescriber, and phase of illness, but extend to healthcare setting and economic state.
- Quality nurse prescribing can improve concordance and ultimately influence disease outcome in a positive way as demonstrated among breast cancer patients on long term hormonal therapy.
- Effective patient-prescriber communication. For women on adjuvant breast cancer hormonal therapy. Wherein the individual patient feels open to discuss their beliefs, values and expectations of therapy and the NP effectively addresses such beliefs and perceptions of continual therapy thus promoting QP.

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