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| RESEARCH ARTICLE

Is there an Effective Delivery of Information in Cancer Patients Participating in Clinical Trials?

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| ABSTRACT

Information is vital to ensure the delivery of effective, patient-centred and quality care. However, healthcare professionals especially those working in clinical trials setting face a lot of barriers that inhibit effective delivery of information. This is because the role of a Clinical Research Nurses (CRN) is slightly different from the traditional nursing role and the challenges these nurses face may be specific to this group. This papers amis to to analyse the role of information in the management of cancer and how it relates to effectiveness of care, and critically analyse the role of a CRNs and the barriers they face in effectively delivering information to patients participating in clinical trials. Literature search was carried out, looking that the role of information in delivery of quality care. Literature relating to role of information in influencing the patient's experiences and the role of the Multi-Disciplinary Team in the delivery of information was reviewed. The review highlighted the importance of information delivery in impowering patients to self-manage not just the disease, but treatment related adverse events as well. The review also highlighted the importance of MDT collaboration to ensure that there is a wide range of expertise that will enable provision of comprehensive patient care and the challenges Clinical Research Nurses face in ensuring delivery of information. Information delivery is vital in ensuring quality care and measures should be put in place to ensure that this is achieved. Clinical research nurses play a vital role in facilitating the delivery of clinical trials and ensuring that patients receive effective patient care. However, the barriers they face in ensuring delivery of information which empowers patients are mainly due to the nature of their role.

| KEYWORDS

Cancer Patients; Clinical Trials; healthcare professionals

| ARTICLE INFORMATION

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1. Introduction

We know that information is vital in ensuring the delivery of beneficial patient-centred and good quality care (Kazimierczak et al. 2013). Information empowers patients, it helps improve their experiences and is considered as one of the key indicators of clinical excellence and safe care (NHS: Institute for Innovation and Improvement 2013). Provision of information influences the patient's experiences of the disease by enhancing their knowledge so that they have the ability to cope with not only the effects of the disease, but also treatment effects (Bennett et al. 2016). Lack of information on how to manage the disease and what to expect from treatment can lead to anxiety, lack of compliance with treatment, inability to cope with symptoms and overall dissatisfaction with care (British Medical Association 2021; Moore et al. 2018). However, it must be acknowledged that there are a lot of barriers that inhibit effective delivery of information by healthcare professionals especially those working in a clinical trial setting. Because of the nature the role of a CRN, the challenges these nurses face may be specific to their role. Ineffective information delivery by CRNs is problematic, especially when clinical trials play an important role in the management of diseases

such as cancer and can form treatment options when there are no other alternatives (Unger J. M. et al. 2016). Therefore, it is important that we get it right. This review will focus on delivery of information by CRNs under the current provisions which enable patients to access treatments. Their role portrays different skill requirements from traditional nursing roles and therefore the challenges these nurses may face will be taken into consideration when reflecting on this issue to ensure all patients' needs are met. This review also specifically focuses on the delivery of information in a cancer setting.

2. The burden of Cancer

Cancer is a disease characterised by abnormal cell division and is known to be the most frequent cause of death worldwide, representing nearly one in six deaths (Hardaker et al. 2017; Compton 2020). Management of cancer is complex because anti-cancer treatment does not just work to stop the ability of the cancer cells dividing and reinforce cell death but also, in the process, the treatment can damage non-cancer cells too (Abbas and Rehman 2018). This leads to ill health and frequent hospitalisation due to unpleasant side effects which increases the strain of cancer on patients, families and the economy as a whole (Lorusso et al. 2017). A recent report from the House of Commons reveals that in 2022, there were 346,217 new cases of cancer diagnosed in England and the number has been increasing each year since 1995 leading to about 27-28% of all deaths in England in a typical year (Rachael Harker 2024).

Despite the development of different types of drug modalities, treatment of cancer remains a challenge because of the adverse events such as nausea, vomiting, infections, hair loss and fatigue. It can also lead to damage of the bone marrow and other major organs, causing reduced blood cell and electrolyte counts (Abbas and Rehman 2018). An adverse event (AE) or a side effect is defined as any unpleasant or unintended experience, symptom, sign or laboratory finding that happens as a result of using a medical product (U.S. Department of Health and Human services 2017). These can be considered as serious adverse events if they lead to hospitalisation, prolonged hospital stays, disability or death (Health Research Authority 2024). Adverse events can have an impact on patients' social, physical and psychological wellbeing (Holland-Hart et al. 2024; Fraterman et al. 2022). AEs such as nausea, vomiting, fatigue and infections can lead to patients feeling very unwell so much that they are unable to manage their activities of daily living or take part in social events (Lorusso et al. 2017). Lorusso et al (2017) further highlight that regular visits to the hospital for treatment can lead to inability to sustain employment leading to financial consequences. Patients receiving cancer treatment therefore are not only concerned about their prognosis, but also the possibility of experiencing adverse events. This will naturally cause further inquisition and a need for reassurance through information receiving which should be transmitted in a compassionate way. For example, the risk of additional AEs within a clinical trial that should be communicated to the patient was demonstrated in the PRIMA study which assessed progression free survival (PFS) benefit of Rituximab maintenance in patients with follicular lymphoma (Bachy et al. 2019). The study revealed that patients receiving maintenance rituximab had a higher rate of adverse events such as reduced blood cell counts and infections compared to those on observation (24.4% vs 16.9%) and also those on Rituximab had a higher rate of serious adverse events compared to those on observation (21.2% v 13.4%) (Bachy et al. 2019). The study highlights the likelihood of patients receiving chemotherapy experiencing side effects which naturally the patient will need thorough information to be delivered in a sympathetic manner. The desire for information affects all involved because these challenges don't just have an impact on the patients but on the care givers and their families who are witnessing the concerning symptoms and are supporting the patient themselves too.

Delivery of information before starting treatment and during the entire patient journey will facilitate the development of the understanding of the disease, their involvement in self-management and any support services that are available to them (Kazimierczak et al. 2013; Fraterman et al. 2022). Therefore, information needs to be sufficient and portrayed in an effective and compassionate manner from the very beginning. Receiving information has the ability to reduce distress because it reduces anxiety and enhances the knowledge to manage the illness better (Chan et al. 2011). This has been supported by a study carried out to assess impact of patient education on patient distress, treatment-related concerns, and the prevalence and severity of chemotherapy side-effects (Aranda et al. 2012). The study revealed that patients who are educated on the management of the disease before receiving chemotherapy were more likely to be prepared with the ability to handle and manage the side effects better. However, this doesn't always happen in clinical practice because of different factors such as lack of time due to busy clinical demands. In many hospitals, CRNs also don't have designated clinic rooms to deliver their service provisions when seeing research participants making it difficult to deliver information effectively. As a result, they tend to make use of whatever provisions they have available which are not always in the patient's best interest such as lack of privacy or a rushed interaction.

Another systematic review aimed to assess the effects of information interventions which orientate patients and their carers/family to a cancer care facilities and support services revealed that patients who received information about the risks and benefits of chemotherapy were more knowledgeable about the side effects of their specific treatments and disease compared with controls (Chan et al. 2011). This highlights the importance of talking and listening to patients and families as equal partners in the delivery of their own care in order to empower and improve their experience (NHS: Institute for Innovation and Improvement 2013). Some of the challenges faced by patients participating in clinical trials, in particular early phase trials is the

lack of information known about the drugs they are receiving. The dosages, side effects, and the effectiveness of the medicinal products are not yet known at this stage (Ogbaudu et al. 2024). This leads to increased anxiety and fear, something which must be considered and supported. Despite not having enough information at this stage, patients still need to be reassured that they will be closely monitored throughout the trial and any new information that is discovered during the course of the trial will be communicated (Orriss-Dib 2021).

3. The role of Multidisciplinary team in information delivery

There is evidence to support that multidisciplinary team (MDT) working has been found to be effective in the delivery of patient care. However, could this be the same for information delivery (Taberna et al. 2020)?

It is questionable whether the responsibility to deliver information to patients participating in clinical trials falls solely on the CRNs within the patients' journey? Information can be delivered by any member of the MDT as long as it's relevant to their role. The principal definition of an MDT is the involvement of specialised healthcare professionals with different expertise and skills who have the overarching aim of improving patient's treatment outcomes (Taberna et al. 2020). These can be doctors, nurses, advanced clinical practitioners, pharmacists, radiologists or therapist. The benefit of using MDT approach is to ensure that there is a wide range of expertise that will enable provision of comprehensive and effective care (Licitra et al. 2016). Therefore, members of the MDT should be encouraged to have full participation in the delivery of information within their specialist discipline too.

Different members of the MDT contribute to patient care in different ways either at the same stage or at different stages of the patient's treatment journey and this has proven effective. A study carried out to analyse the differences in outcome and survival data between patients seen by MDT compared to non-MDT revealed that patients reviewed by members of MDT were significantly more likely to receive the best treatment options (Friedland et al. 2011). The benefit of having multi expertise involvement in the delivery of care is that the patient also receives wide range of information and support from the different professional as long as referrals have been made when need is recognised (Lin et al. 2018). A good example is referral to charities such as Maggies and Macmillan. Maggies is a charity that provides specialised cancer support services such as psychologists, benefit advisors and they provide a friendly environment for patients and families who need support and guidance. Information about support services and charities should be made available to all clinical trial participants too. It could be argued that this information is just as vital to provide as disease specific information for example, offering reassurance and comfort in stressful times. However, due to the unequal distribution of services across the nation, not all patients get access to such provisions which can be detrimental to their needs.

We know that nurses are valuable members of the MDT and have the responsibility of ensuring that patients' needs and preferences are communicated (Nursing and Midwifery Council 2018). They also have the responsibility to advocate for patients in MDT meetings should there be factors that may be identified to unduly influence patient's decisions (Nursing and Midwifery Council 2018). The nursing profession has been built on assessing, planning, implementing and evaluating care (Ajibade 2021; Nursing and Midwifery Council 2018). This gives nurses the ability to observe and assess patient's needs so that they are able to educate, reinforce information already delivered by the medical team and also make referrals to other members of the MDT. Nurses are also often the first point of contact for patients and have the responsibility to deliver effective care through training on the use of devices, treatment regimens and education of self-management. They have a vital role in building rapport with patients and providing person-centred care that promotes health and disease prevention through patient education (Nursing and Midwifery Council 2018). This indicates that the nurse has a very big role in delivering information and this can be done on every opportunity of patient contact. However, this is not always the case in clinical practice. Some of the factors hindering delivery of information are lack of time which is usually caused by staff shortages and nurses having to split their time and attention to several tasks at any one moment (Helen Tamburello 2023).

4. The role of a clinical research nurse

Specifically, clinical research nursing is a type of nursing practice that mainly focuses on the care of research participants (Kunhunny and Salmon 2017). CRNs play a very important role in the recruitment of patients to research studies, data collection and provision of nursing care to patients participating in clinical trials (Xing et al. 2024). In contrast to the traditional nursing role, the specific clinical duties, competencies and training requirements for CRNs are still not very well defined and have been found to be varied in different specialities and geographical areas (Kunhunny and Salmon 2017; Xing et al. 2024). CRNs have the responsibility to deliver research protocols with integrity and accuracy whilst ensuring the safety of research participants (Kunhunny and Salmon 2017). They provide information to patients on different clinical trials to ensure that they are well informed before participating in the studies and ensuring that their rights are respected. However, in most cases, information delivery and informed consent for clinical trial patients is mainly tailored to ensuring that patients understand the purpose of the study, the design of the study, the risks and the benefits of the medical products under investigation (Manti and Licari 2018; Orriss-Dib L 2021).

Reflecting on clinical practice, patients participating in clinical trials are mainly looked after by medical doctors and CRNs. Despite having the clinical responsibility to deliver effective nursing care, CRNs can be fixated on delivering care which is only protocol driven (Xing et al. 2024). If the patients are also still under the care of the clinical specialist nurses, CRNs will always take it for granted that specialised aspect of the nursing information such as assessing patient's home circumstances and need for support services will be delivered by clinical specialist nurses. However, in most cases, when patients consent to clinical trials, their care will usually only be delivered by people who have been trained and delegated to work on that particular study. This means delivery of specialised information which is mainly delivered by clinical specialist nurses may not be adequately given to patients. CRNs are recruited to deliver research and experience in a particular speciality is usually desirable but not essential. Therefore, a basic understanding of the disease is usually enough to ensure that the nurse can deliver research safely as per protocol (Orriss-Dib L 2021). This can lead to knowledge gap and lack of experience in delivering the right information which holds consequences of lack of informed knowledge to patients, and heightening anxiety and stress as previously discussed. Examples of information they miss out on are generic toxicities, contact points for help if they need psychological or social support.

Factors such as delivery of care to research participants only being restricted to delegated staff can lead to inadequate communication due to minimising people who can interact with the patient, and assumed care which may not have been clarified in advance (Ndoro 2014; Friedland et al. 2011). A study was carried out to evaluate the effect of the MDT model on Colorectal cancer patients managed by MDT compared to non-MDT managed patients (Lin et al. 2018). Apart from giving out written education booklets, this study had case managers whose role was to carry out telephone consultations to determine educational and social needs of each patient. Information delivery and referral to other healthcare professionals such as nutritionist, social workers, and other support services was dependent on the individual needs of the patients. The study revealed that the follow-up appointment compliance rates after discharge were significantly higher for the MDT group (first week (99.7% vs. 97.8%), first month (99.1% vs. 95.7%), and third month (98.8% vs. 88.9%)) compared to those for the non-MDT group and average survival time of the MDT group (48.51 months) was longer than that of the non-MDT group (36.57 months). The results of this study cannot be generalised because the study was a retrospective study and therefore more research would need to be undertaken. However, having case managers who had an exclusive role of delivering information and ensuring that follow-up was made to assess any further needs led to improved clinical outcomes. This study highlighted that having clearly specified roles is essential in ensuring that information is delivered and appropriate referrals to expert MDT members are made. This is what we should strive, and make provisions for in current care. However, one of the biggest barriers to having extra members of staff to deliver specific duties are financial constraints in the healthcare system.

In order to counteract the gap in knowledge in CRNs, the most ideal situation is to see MDT collaboration where specialist nurses have Good clinical practice (GCP) and specific research study training so that they also get involved in the care of trial participants. GCP is defined as a set of internationally-recognised ethical and scientific quality guidance that must be followed when designing, conducting, recording and reporting clinical trials that involve human beings (Gov.uk 2014). In order to ensure quality in research data, only professional who have GCP and specific study training are allowed to carry out any trial related activities. Allowing specialist nurses to have specific research study training will enable research nurses to have the opportunity to tap into the specialised knowledge and skills without seeing the integrity of actual clinical trials jeopardised. This will also enable patients to receive full comprehensive care when all information provisions are covered. However, it could it be argued that, is there a place for CRNs if Specialist Nurses are taking on more responsibility for clinical trials too? This has been highlighted as one of the hindrances in involving other members of MDT into the care of clinical trial participants. However, despite all these restrictions, there is still room for finding ways for MDT collaboration in order to ensure that research participants receive high quality information to help them manage the illness and associated toxicities experienced by the investigating medicinal products.

Experience in cancer care is an essential requirement for CRNs looking after cancer patients and they are known to be highly skilled practitioners by virtue of their specialist clinical knowledge and comprehensive understanding of research process (Kunhunny and Salmon 2017). However, there is no formal mandatory research training required to become a CRN and the nature of induction and training offered is different from hospital to hospital and it can be different from team-to-team as well. When looking at clinical skills training, CRNs also undergo the same training and competence assessment as nurses working in a non-clinical trial setting. However, due to the nature of the role, maintaining the clinical skills competences can be a challenge because the care they deliver is usually dependent on the nature of trials that are running at a given time and the type of procedures and skills required to deliver those studies (Kunhunny and Salmon 2017). This means research nurses may receive training to educate patients but their inability to maintain the knowledge and skills becomes a hinderance in ensuring that they are able to adequately deliver the right information to patients receiving chemotherapy. Therefore, it is recommended that attending regular training and updates will help improve knowledge and skill to deliver information (Kallio et al. 2020). CRNs also have the responsibility to ensure that they acknowledge their limitations and take advantage of the expertise of other members

of the MDT in providing specialised information and support. Other barriers to information delivery can be failure to attend training due to staff shortages. This can be managed by putting in place measures such as frequent in-house short episodes of training such as short presentations organised by senior colleagues that will help improve compliance with training.

Information delivery is effective when delivered in a timely manner because too much information delivered to a newly diagnosed cancer patients may not be useful and can also be undesirable (Chan et al. 2011). However sometimes, CRNs recognise that their resources are limited and try to share all their knowledge in one transaction through fear of not knowing when they would next have the opportunity to share the information again. However, patients diagnosed with cancer will be overwhelmed, afraid and in a state of denial in the early days following the diagnosis. Because of the nature of the diagnosis, treatment decisions have to be made as soon as possible. They have prolonged discussion about the diagnosis, how long they have to live, the treatment options available and at the same time, they are given long pages of clinical trial participant information sheets to read. A review of literature related to cancer care revealed that information delivered to cancer patients should be specific to personal circumstances and should comprise of what to expect during treatment and how to identify and manage side effect (Kazimierczak et al. 2013). It is therefore important for the person delivering information to be sensitive enough to recognise the need to have different sessions for information delivery. It is also important to be mindful that patients participating in clinical trials will have more information to take on board with the awareness that this is a trial and therefore there are certain elements unknown.

Due to protocol requirements, clinical trials participants need different type of information at different stages. They receive participant information sheet which includes reason for the study, the conduct, the risks and the benefits of the study at the time when treatment options have been decided (Orriss-Dib L 2021). If they are taking part in trials involving different treatment arms, they may not know what treatment they will be allocated to until they have been randomised. Randomisation is the random allocation of trial patients to treatment arms in order to eliminate accidental bias and provides a base for allowing the use of probability theory (Lim and In 2019). Sometimes, treatment allocation may not take place until 4 weeks after signing informed consent. It is therefore important that delivery of information about treatment and possible side effects is properly planned in order to ensure understanding and uptake of the right information at the right time. So as not to overwhelm individuals and ensure the right information is considered, and focused on, at appropriate time points.

Having structure and standardization of when, how and what information is delivered at a given time is also very important (Marshall et al. 2009). This enables clarity and consistence on what information needs to be delivered at the different stages of the patient's treatment journey (Westrum 2014). Structure involves having a list of pre-planned topics as a guide to what information should be communicated and standardization makes delivery of information uniform (Marshall et al. 2009). The depth of the detail in the information delivered on the topics will always be dependent on the individual information needs of the patients. A systematic review involving 14 studies aimed to determine the effectiveness of educational interventions for managing cancer-related fatigue in adults revealed that relevant topics required by patients and their families were as follows: diagnosis, prognosis, side effects, and self-management areas such as physical activity, nutrition, fertility, management of work and supportive care (Fraterman et al. 2022; Holland-Hart et al. 2024). This gives an idea of what information is required by patients. Having a structured approach on how and what information should be delivered can ensure consistency and delivery of the appropriate information required to meet the needs of individual patients (Marshall et al. 2009).

Information delivery is a continuous process and needs to be reinforced in all consultations (Holland-Hart et al. 2024). Taking into consideration the psychological effect of a cancer diagnosis and the difficulties is simulating all the information given either at diagnosis or at the start of treatment. Information needs to be repeated in order to ensure that the patient has understood. A study carried out to explore information pathways and describe how information continuity was delivered to older patients with complex care needs revealed that patients always had difficulties grasping all the information delivered at one given time (Kneck et al. 2019). The study highlighted the need for information to be made available when patients were discharged from hospital. It was also recommended that information should be made available in different forms so that patients can have the opportunity to revisit the information if required. Information can be delivered in written form, audiovisual aids, telephone helplines, face to face counselling sessions or teaching (Chan et al. 2011). In order to ensure information continuity, clear documentation, record keeping and handovers is very important (Kneck et al. 2019). Yet, this is something so troublesome to maintain in the current busy climate of the health care system with resources being limited and therefore we need to consider provisions to improve.

5. Conclusion

Quality care is about providing a service that listens to the patients and families, identifies their needs, and then utilises the skills and expertise of the MDT. Information delivery is essential for informed decision making and to ensure that patients are educated to manage the disease and treatment effectively (Moore et al. 2018). It is therefore important to ensure that measures are put in place to improve the way information is delivered as it notably makes a huge difference to patient experience.

Clinical research nurses play a vital role in facilitating the delivery of clinical trials, ensuring that cancer patients receive effective patient care and have the ability to self-manage the disease and any treatment effectively. However, they face a lot of challenges because of the nature of their role. Their experience and skills are sometimes limited due to the nature of studies they are delivering. In order to ensure that they deliver information which is individualised to meet specific patient needs, having a structure of when, how and what type of information is delivered is important (Marshall et al. 2009). In current practice, how and when information is delivered to clinical trial participants is done at the discretion of individual nurses. However, having a standardised process would ensure delivery of timely information and aid identification of individual patient needs that could lead to appropriate referrals for support services.

Most of the evidence reviewed involve studies looking at non clinical trial patients and there is also very little or no evidence to show the quality of information patients participating in clinical trials receive. Therefore, further research to determine the quality of information patients participating in clinical trials receive compared to patients being looked after by other members of the MDT is recommended. Further research to determine the barriers clinical research nurses face in delivering information is also recommended to help progress this initiative forwards. This demonstrates the lack of awareness of such specialist skill applied in this area.

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