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**Title: Reducing inequalities in care for patients with non-malignant diseases –
insights from a realist evaluation of an Integrated Palliative Care Pathway**

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Abstract

Background: The need for palliative care is growing internationally with an increasing prevalence of non-malignant diseases. The integrated care pathway was implemented in primary care by multidisciplinary teams from 2009 in a locality in the North East of England. Fourteen GP practices provided data for the study.

Aim: To find if, how and under what circumstances palliative care registrations are made for patients with non-malignant diseases in primary care.

Design: GP practice data were analysed statistically and qualitative data was collected from health care professionals and members of relevant organisations.

Findings: A mixed effects logistic model indicated a significant difference beyond the 0.1% level ($p < 0.001$) in registrations between the malignant and non-malignant groups in 2011, with an odds ratio of 0.09 ($= \exp(-2.4266)$), indicating that patients in the non-malignant group are around 11 times (1/0.09) less likely to be registered than patients in the malignant group. However, patients with non-malignant diseases were significantly more likely to be registered in 2012 than in 2011 with an odds ratio of 1.46, significant beyond the 1% level. Qualitative analyses indicate that healthcare professionals find registering patients with non-malignant diseases stressful, yet feel their confidence in treating this population is increasing.

Conclusions: The ICP began to enable the reduction of inequalities in care by identifying, registering and managing an increasing number of palliative patients with non-malignant diseases. Consensual and inclusive definitions of palliative care were developed in order to legitimise the registration of such patients.

What is already known about the topic?

- The need for palliative care remains much larger than the actual available provision internationally, and this is being acknowledged by policy makers and influential bodies (1-5).
- Deaths from chronic and non-malignant disease exceed those from cancer and this difference is likely to grow as the population ages (6).
- Identifying patients with non-malignant diseases who have palliative care needs is challenging for health care professionals, these patients have relatively uncertain prognoses related to survival and uncertain disease trajectories (7, 8).
- Population based studies using random samples of deaths and bereaved carer reports indicate that there are more symptom issues in the last year of life in those suffering from progressive non-malignant diseases than those suffering from malignant diseases (9).
- It is unknown how and in what circumstances patients dying with non-malignant diseases can be identified successfully.

What this paper adds?

- This study highlights that there is a discrepancy between the number of palliative patients with malignant and non-malignant diseases identified in primary care; patients with malignant disease are often easier to identify, register and manage.
- It is essential that definitions of palliative care are inclusive of those patients with non-malignant diseases in order to identify appropriate palliative care patients and provide care equality.

- Health care professionals in primary care have low confidence and high stress when placing patients with non-malignant diseases on a palliative care register.
- Education that legitimises non-malignant patients as appropriate for palliative care will increase the appropriate identification of such patients.

Implications for practice and policy

- The prevalence of non-malignant diseases is increasing internationally (10); calling for policy makers to balance past emphasis on malignant disease with policies and guidance for practitioners worldwide to support dying patients with non-malignant diseases.
- The combination of increased prominence of long term conditions and older populations is calling for care systems to respond appropriately to ensure equity in provision.
- The Department of Health in England produced the End-of-life care strategy (2) in response to these challenges, as it assumes that all patients with palliative care needs will be treated the same regardless of diagnosis. This research highlights that more emphasis is needed to translate this ideal of universal provision into practice.

Background

In a semirural locality in the North East of England, fourteen GP practices covering a population of 78,000 implemented an Integrated Care Pathway (ICP) in order to improve palliative and end-of-life care in 2009/10. The ICP is still in place and is coordinated by a multidisciplinary, multi-organisational steering group with service user involvement. It is delivered in line with national strategies on Advance Care Planning (ACP) and end-of-life care (2, 3) and aims to provide high quality care for all conditions regardless of diagnosis. It requires each GP practice to develop an

accurate electronic register of patients through team discussion using an agreed palliative care code, emphasising the importance of early identification and registration of those with any life limiting illness. This enables registered patients to have access to a range of interventions such as advance care planning, anticipatory medication and the Liverpool Care Pathway for the dying patient (LCP) (11). In order to register patients, health care professionals use the ‘surprise question’ which aims to identify patients approaching the last year of their life (12). The register is a tool for the management of primary care patients; it does not involve family and patient notification. Practice teams then use a palliative rather than a curative ethos in consultation by determining patients’ future wishes.

Descriptive GP practice data analysis had indicated that palliative care registrations had increased since the implementation of the ICP but more detailed analysis was required. The study reported here explores:

- Whether patients with non-malignant diseases were as likely to be registered as patients with malignant diseases. Explanation was sought for any discrepancy.
- Whether there were more registrations of patients specifically with non-malignant diseases since the ICP had been implemented.
- The conditions necessary for equitable palliative care registrations.

Methods

This study used realist evaluation (13), with its focus on ‘what works, how, in which conditions and for whom’ (14) (15). Realist evaluation acknowledges that interventions take place within complex social systems (16) and is therefore well suited to studying interventions (or programmes) with complex and potentially multiple pathways from implementation to impact. The concepts of Context, Mechanism and Outcome are used to develop programme theories of how the intervention is

supposed to work (13). Mechanisms are understood as being a combination of the resources offered by an intervention and the reasoning this enhances in a particular context (17). This alters the behaviour of participants, which leads to measurable or observable outcomes. Empirical data is used to test the programme theories to identify how the intervention actually works in practice. (17).

Our initial programme theory for the ICP stated: Palliative care registrations should increase regardless of disease type (outcome) due to a focus on identifying patients early using the palliative care register (mechanism) in a health care domain that appreciates the palliative care needs of patients (context).

In order to ‘test’ this theory, quantitative data analysis explored variations in palliative care registrations across GP practices and then qualitative data explored potential explanations for why variations in outcomes might have occurred.

Routinely collected locality Death Audit data was accessed for 2011/12. Patients were added to the register as part of routine care, by their GP who also determined disease type. Logistic regression models are used throughout the paper. The response of interest is the number of registrations out of the total number of patients, which can be considered as a binomial random variable. The explanatory variables of interest are the cancer type (malignant versus non-malignant) and time (2012 versus 2011). The sample consisted of all palliative care patients who had died in 2011/12 from fourteen GP practices. Any differences between practices are accounted for by including the practice as a random effect in a mixed effects logistic model. The software used for the analysis was R 3.2.0 (18).

Three focus groups were conducted throughout 2013. Participants were recruited from the locality implementing the ICP via email to each GP practice manager. Focus Group 1 (FG1) aimed to highlight how the ICP functioned in practice (twelve attendees: three GPs, two community matrons, two ward staff nurses, one social care team lead, one junior doctor, one palliative care unit project manager,

one palliative care unit deputy manager, one team leader for the OOH nursing service). FG1 led to a detailed mapping of the ICP interventions (19). The maps were set against perceptions of a different set of practitioners in Focus Group 2 (FG2). FG2 had eight attendees (two GPs, one MacMillan nurse, one ward staff nurse, one community matron, one social care team lead, one district nurse, one palliative care unit deputy manager) who refined them. The maps were further refined in Focus Group 3 (FG3), which had six attendees (four GPs, one care home manager, one social care team lead).

The study was granted full ethical approval from the NHS Research Ethics Committee (NRES) on 13.12.2011. Permission was sought to use GP practice data from 14 GP practices and the Research and Development (R&D) manager at NHS North of Tyne PCT. Written informed consent was obtained from all participants.

Findings

Differences in registrations between malignant and non-malignant diseases.

Initial histograms using percentages of palliative care patients who subsequently died identified a substantial difference between the number of patients registered with malignant and non-malignant diseases. Figure 1 shows that substantially more patients with malignant diseases are put on to the register than patients with non-malignant diseases, in all practices. However, there is significant variability between practices; for example, Practice A registered no patients with non-malignant disease who subsequently died, whereas Practice D registered around half of those with non-malignant disease who subsequently died.

INSERT FIGURE 1

A mixed effects logistic model indicated a significant difference beyond the 0.1% level ($p < 0.001$) in registrations between the malignant and non-malignant groups in 2011, with an odds ratio of 0.09 (= $\exp(-2.4266)$) indicating that patients in the non-malignant group are around 11 times (1/0.09) less

likely to be registered than patients in the malignant group. The associated (approximate) 95% confidence interval (0.06, 0.13) suggests that , after allowing for uncertainty patients in the non-malignant group are less likely to be registered than malignant patients with 7- to 17-fold.lower odds.

We also observe considerable heterogeneity amongst practices with a variance of 0.41. The mixed effects model offers a demonstrably improved fit compared to the main effects model when comparing their values of Akaike's Information Criterion (AIC).

This analysis therefore supports Figure 1, in showing that significantly more patients with malignant disease were registered in 2011 than those with non-malignant disease. This is despite more people in the general population dying of non-malignant diseases.

The use of ratios allows for comparisons of malignant and non-malignant palliative care registrations irrespective of practice population size. For example, using ratios, a score of 1 would mean that all patients with malignant diseases who died in 2011 were on the register. A score of 0.5 would mean only half of these patients were registered.

In support of the outcome of analysis 1, FG3 highlighted that health care professionals found registering patients with non-malignant diseases stressful. This is due to their non-predictable trajectory, the difficulty in considering non-malignant patients as appropriate for palliative care and the lack of health care professionals involvement in treating progressive symptoms, all of which made registration a stressful decision (reasoning).

GP4 (FG3): *"There is stress with non-cancer registrations. With a cancer diagnosis you have a fixed underlying illness I think haven't you? That the family are aware of and recognise that their relatives are generally going downhill. But with a non-cancer diagnosis you know they might have had heart failure for years and years and years and yes they're getting a bit worse but they've had this diagnosis for years."*

The uncertainty linked to a decision to register in such a case means that professionals may be less confident about such registrations, and therefore use them less systematically.

GP5 (FG3): *"But I still find it difficult in my head because there's a blip, you're just not as confident in putting someone on the board (register) when they're non-cancer than you are if they're cancer. You're just not confident about where the end point is going to happen, how it's going to happen, what it's going to be like, so there is kind of a confidence thing about it."*

In addition to this, the traffic light system (resource) used in the locality is not as useful when caring for patients with non-malignant disease trajectories. This is a local tool, where green signals the patient with a life limiting illness is well, amber signals a decline and red identifies end-of-life. Patients with non-malignant disease often move between traffic light stages non-linearly meaning that if a patient is in 'green' they could quickly deteriorate to 'red' being nearer the end-of-life, but their condition could improve with treatment, becoming 'green' again. This is unlikely to happen to patients with malignant diagnoses. Thus, the unpredictable trajectory of non-malignant diseases (context) makes decisions about when palliative care is appropriate particularly difficult and may help to explain why health care professionals' confidence in managing this patient group is low. Furthermore, health care professionals described difficulties in viewing patients with non-malignant diseases as appropriate for palliative care.

GP1: *"I think it's very difficult (definitions of palliative care) and it's something we've endlessly discussed in our practice, and the nomenclature is very confusing, and I think cancer treatment makes it even more confusing, for example breast cancer, is often palliative but it doesn't mean that, they may live a long life, it's like a chronic illness isn't it, the definition of palliative has to start to change, it's very difficult, you know, what do you call people? I use the palliative care register and*

then people get confused that I mean the very end- of-life, the Liverpool pathway, it is very confusing."

Community Matron (FG2): "*And I think that erm, maybe sometimes we do tend to, when you say palliative care, you do think of cancer diagnoses whereas your COPD and heart failures and things like that, and I think they're quite difficult from our perspective to know when, you know if they have an exacerbation then yes they're really struggling but the next week they could be fine so at what point do you think well, they might be ready for the pathway (ICP)?"*

The quotes highlight that a GP or community matron who has a palliative care definition inclusive of non-malignant diseases may be more likely to register such patients with palliative care needs (context). At the commencement of the ICP healthcare professionals regarded palliative care as restricted to the care delivered at the actual end-of-life (last 3 days) and struggled to incorporate those with non-malignant diseases into their definition of palliative care. Important debates then began across the locality concerning the definitions of palliative and end-of-life care. This, along with other educational interventions, began to change the culture, with proactive palliative care implemented, allowing interventions to be implemented in advance of the actual end-of-life. Definitions of and differences between palliative and end-of-life care constitute a debate that is outside the remit of this article, but that needs to be acknowledged as having an effect on practice.

In light of these findings, the programme theory was refined to: The unpredictable trajectory of non-cancer illnesses and difficulties in considering non-cancer patients as appropriate for palliative care (context), mean that the traffic light system (resource) is less useful when treating those with non-malignant diseases. This results in health care professionals having less confidence in registering patients with non-malignant disease (reasoning) and therefore

significantly less patients with non-malignant disease were registered in 2011 (outcome), as illustrated in Figure 2.

INSERT FIGURE 2

Increasing registrations of patients with non-malignant diseases

Data from the 2011 and 2012 Death Audit allowed the number of people who died of malignant and non-malignant diseases that were on the register to be identified. To identify if registrations of non-malignant patients were increasing over time, 2011 data was compared to 2012 data. Table 1 provides an overview of all deaths in the locality, broken down by registration and disease type. This table indicates that the registration of those with non-malignant diseases was increasing from 2011 to 2012.

INSERT TABLE 1

Ratios were calculated for 2011 and 2012 and for each GP practice, using 1) their malignant deaths on the register divided by the total malignant deaths that year and 2) the non-malignant deaths on the register divided by all non-malignant deaths that year. The mean and standard deviations for these ratios are presented in Table 2. The malignant ratios for 2011 and 2012 were then compared, and the non-malignant ratios were then compared with each other. Ratios were created in order to account for differences in practice population sizes.

For the malignant group the odds ratio for registrations in 2012 compared to 2011 is 1.78 and is significant at the 5% level. The approximate 95% confidence interval for this odds ratio is (1.09, 2.88), suggesting that the odds of registration are between 9% and 188% higher in the malignant group. The random effects variance of 0.40 indicates that the levels of registrations in the fourteen

practices are quite different. Values of AIC from the mixed effects model demonstrated its superiority over its fixed effects equivalent.

From 2011 to 2012, GP practices therefore significantly increased the registrations of patients with malignant diseases (outcome).

INSERT TABLE 2

In the non-malignant group, patients were significantly more likely to be registered in 2012 than in 2011 with an odds ratio of 1.46, significant beyond the 1% level. The odds of registration in this group have increased from between 10% to 93% after allowing for the uncertainty from the approximate 95% confidence interval. Considerable variation between practices was observed via the random effects variance of 0.57. Due to this larger value than in other analyses, the difference between the fixed effects model and the mixed effects model was larger here with preference once more (based on AIC) given to the mixed effects model.

From 2011 to 2012, GP practices significantly therefore increased the registrations of patients with non-malignant diseases (outcome).

These two statistical tests indicate very important outcomes; between 2011 and 2012 practices significantly increased the number of patients registered with both malignant and non-malignant disease.

Due to (1) the already very high rate of registrations in patients with malignant disease recorded in 2011 and 2012, and (2) health care professionals confidence in providing palliative care for this group, investigation into increases in the registrations of patients with non-malignant diseases was focused upon. FGs highlighted that health care professionals now had more understanding about non-malignant diagnoses and the relevance and need for appropriate palliative care. This was following the publication of the End of Life Care Strategy (2), formal educational events, educational

outreach visits to practice teams (including discussion of nomenclature), feedback of key comparative data to teams and informal learning from the ICPs founder.

GP3 (FG3): *"I think its education, really. We've been educated that we can now think that non-cancer patients require palliative care. And the permission, it's the permission that you can consider non-cancer patients as palliative."*

Health care professionals felt that these forms of education (resource) had legitimised their decision to put patients with palliative care needs on the register regardless of diagnosis, which increased their confidence to provide palliative care interventions to all appropriate patients (reasoning).

The increasing numbers of people who will die from non-malignant disease means that the identification and registration of those with palliative care needs has to be of same standard as those with malignant disease. The participants in FG3 commented upon the changes in cause of death in the UK, including increased deaths of patients from non-malignant disease (context).

GP4 (FG3): *"I think the other thing as well is that people, not just cancer patients but patients with other terminal illnesses such as heart failure due to modern medicine are living longer than they ever did and this has kind of filtered down, as in days gone by hospices would only take cancer patients whereas now hospices will take people with end stage heart failure or end stage COPD and things and that's because they've lived longer than they would have done historically."*

However, focus groups highlighted that some health care professionals still have uncertainties about the applicability of palliative care to all illnesses, particularly acute exacerbations of a chronic illness such as heart failure and Chronic Obstructive Pulmonary Disease (COPD). Yet, in FGs most health

care professionals stated that palliative care for those with non-malignant diagnoses was important. This suggests that they are aware of the difficulties associated with non-malignant diagnoses and the need for and importance of palliative care for these patients. A GP referred to the increasing recognition of patients with non-malignant disease being appropriate for palliative care (reasoning).

GP4 (FG3): *"That's why more non-cancer patients are being registered. And because historically we wouldn't have thought of it, palliative meant cancer patients. I think that's the biggest factor."*

Figure 3 depicts this; in the context of changes in cause of death and legitimisation that palliative care is appropriate for all with terminal illnesses (context) both formal and informal education (resource) increased self-efficacy in health care professionals registering and providing high quality palliative care to patients with non-malignant disease. This resulted in a significant increase in non-malignant registrations from 2011 to 2012.

INSERT FIGURE 3

Conclusions

Data has shown that there are difficulties in providing palliative care for all patients who need it, due to the difficulties of prognostication with non-malignant illnesses. This causes uncertainty and stress for health care professionals when deciding to register patients, resulting in less people with non-malignant diseases being registered. However, overall, health care professionals in the locality are increasing their use of palliative care registration. Due to the already high rate of registrations in patients with malignant disease, reasons for increases in those with non-malignant disease were

pursued. The findings from FGs highlighted that staff are building confidence in registering patients with non-malignant disease and this has been legitimised through local policy and practice.

This study uses mixed methods in order to uncover not only whether palliative care registrations are increasing, but also for whom, by what means and in which circumstances. It offers rich data of use to researchers, health care professionals and policy makers. However, the findings are based in one primary care locality and therefore cannot be generalised without caution. They indicate that identifying patients with palliative care needs due to non-malignant disease is difficult and attributes this to the unpredictable illness trajectory (7, 8) but does not highlight other barriers to the identification of these patients nor effective mechanisms for change.

The Office of National Statistics reports that in 2013, cancer was the most common broad cause of death (29% of all deaths registered) (20). However, diseases of the circulatory system and respiratory system accounted for 43% and ischaemic heart disease, stroke, lower respiratory infections and chronic obstructive lung disease have remained the top major killers during the past decade (5, 10). The prevalence of dementia is also expected to increase, from 800,000 in 2012 to 1,000,000 in 2021 in the UK (21). This evidence, alongside the knowledge that the population is ageing (22) and cancer treatment is advancing (23), suggests that cancer deaths will continue to decrease and non-malignant deaths will increase in the future. It is therefore increasingly important for those in clinical practice to reduce inequality by identifying, registering and managing patients with palliative care needs who have non-malignant disease to the same standard as those with malignant disease. In order to do so, the transition between curative and palliative care needs to be better understood for those with non-malignant disease.

Future research could address whether the recognition of palliative care patients with non-malignant diseases is growing nationally. Further exploration of the mechanisms by which this is occurring, potentially investigating more meso, organisational level mechanisms would be a promising research avenue. The need for good quality palliative care services for those with all

diagnoses is growing internationally and requires increased skills, expanded capacity, integrated services, involvement of the wider community and collaborative working.

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Conflict of Interests Statement

The Authors declare that there is no conflict of interest.

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