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Pharmacist perceptions on the need for a quality guidance resource for pharmacy service provision in the neonatal intensive care unit – comparison between Poland and Australia

ABSTRACT

OBJECTIVES: There is no global consensus on services and roles that should be performed by a clinical pharmacist in the neonatal intensive care unit (NICU). Furthermore, there are no quality guidance resources or key performance indicators available to guide pharmacist practice in this setting. The purpose of this research was to explore pharmacist perceptions on the need for, and development of, a NICU-specific quality guidance resource containing key performance indicators for pharmacy service provision.

METHODS: Semi-structured interviews were conducted with directors of pharmacy as well as neonatal pharmacists in Poland and Australia. The interviews were conducted between February and August 2017.

KEY FINDINGS: Overall, three key themes were categorized around the study objectives: 1) Lack of guidance in the provision of NICU pharmaceutical care services, 2) Embracing a pharmacist-specific, quality guidance resource for the NICU and 3) Constraints limiting the use of quality guidance resource. None of the participants from either country were able to identify any readily available NICU specific quality guidance resources for pharmacists. However, the majority of participants from both countries were open towards the development of a quality guidance resource and felt that this would be useful. Differences between countries were noted when considering the type of pharmacy practice models functioning in each country and the perceived barriers to implementing the proposed quality guidance resource into practice.

CONCLUSION: Although there are significant differences in the type of pharmacist practice systems functioning in each country, pharmacists in both Australia and Poland

demonstrated significant support for the development of a quality measurement tool to guide and structure practice in the NICU, and recognised benefits to its implementation. Future efforts should focus on the development of quality measures that can be adapted to different NICU settings, both on a national and international scale.

KEYWORDS: Clinical pharmacy, NICU/neonate, quality measurement/KPIs

INTRODUCTION

The management of pharmacotherapy within the neonatal intensive care unit (NICU) is complex and requires the guidance of a pharmacotherapeutics expert.¹ Due to their unique characteristics, comprising considerable inter-individual differences in pharmacokinetics, birth weights and gestational ages, neonates are particularly vulnerable to sustaining medication errors.² Furthermore, this patient population is prone to experiencing significant consequences as a result of medication misadventure.² As such, the role of the pharmacist within the specialist area of neonatology is continually advancing towards more direct involvement in patient care.³ Indeed, the benefits of pharmacist interventions include reduced incidence of medication errors, optimisation of total parenteral nutrition (TPN) regimens and better rationalisation of pharmacotherapy.⁴⁻⁷

It is evident that pharmacist practice varies in NICU settings both on a national and international scale.⁸ A recent study by Krzyżaniak et.al. highlighted that pharmacy services delivered to NICU settings in Poland and Australia differed significantly, with the focus of practice in each country centred on dispensary-based and clinical, ward-based services respectively.⁹ Further research by Pawłowska et.al. investigating general hospital pharmacy practice in Poland, supports these findings and demonstrates that the concept of clinical pharmacy is not yet widely adopted in Polish hospital settings, and pharmacists are often stationed predominantly in the dispensary and limited to medication supply roles.¹⁰ In contrast, Australian studies suggest that pharmacists are integrated into the interdisciplinary team and have a large input into ward-based pharmacotherapy-related decision-making as well as other clinical roles including medication chart review and therapeutic drug monitoring (TDM).^{11,12} This variability in practice may impact upon the outcomes achieved by vulnerable neonates.

There have been efforts made from the International Pharmaceutical Federation (FIP) and the World Health Organisation (WHO) to improve the standardisation of pharmaceutical care services through the publication of standards, such as the Good Pharmacy Practice (GPP) guidelines.¹³ However, it is apparent that there are no guidelines available to direct pharmacists in their clinical practice in specialty areas of pharmaceutical care, such as the NICU.¹³ A literature review reported that there are currently no established key performance indicators (KPIs) to serve as a point of reference for neonatal pharmacists.¹⁴ Whilst existing standards for pharmacy practice in critical care settings might have applicability, as well as non-pharmacist guidelines from neonatal societies, pharmacist-specific NICU-based guidelines are particularly important in the care of critically ill infants for the provision of a consistent and quality pharmacy service.^{15,16} KPIs are an effective means of gauging the quality of healthcare services being provided and in determining the potential to improve this level of care for patients.¹⁷ They also have the potential to standardise care provided in comparable hospital settings, through the process of benchmarking.¹⁸

Due to the apparent variability in pharmacist practice in NICU settings within and between countries, there is a need for KPIs or quality practice guidance resources to be made available to promote the standardisation of pharmacist practice in this high-risk and fragile patient group.⁸ As there is currently a lack of NICU-specific quality frameworks targeted at pharmaceutical care services, it is important to gain an understanding of whether pharmacists working in these settings require or even want a resource of this nature to be developed. It is prudent to understand pharmacist perceptions not only within but also between countries, and comparing those with a more advanced level of pharmacy practice to nations that are refining their hospital pharmacy services. This form of comparison will enable the identification of overlapping perceptions, and potentially strengthen the argument for the development of a global resource. Therefore, this study aims to canvass

pharmacist attitudes from two industrialised countries with differing pharmacy service structures - Poland and Australia - towards the development of a quality guidance resource to assist in the medication management process in neonatal patients.

Specific objectives included:

1. Determining whether pharmacists currently used any practice frameworks or models to guide their practice in the NICU
2. Determining whether pharmacists felt a need for a quality guidance resource to be developed
3. Identifying potential barriers and benefits to the implementation of this resource into practice in each country

METHOD

Study design

A qualitative study, comprising semi-structured individual interviews with Australian and Polish NICU pharmacists, hospital pharmacists and directors of pharmacy was undertaken between February and August 2017. A qualitative approach was used as it was deemed the most suitable method for this exploratory research, enabling a fuller understanding of the context behind pharmacist opinions and attitudes, as well as the perceived needs of pharmacists in improving existing practices and beliefs. Ethics approval was sought and obtained from the respective human research ethics committees at the University of Technology Sydney (UTS), Australia (UTS HREC REF NO. ETH16-1033) and the Medical University of Gdansk (GUMed), Poland (GUMed HREC REF NO. NKBBN/424/2016).

Participants were assured of confidentiality and were informed that their responses would be de-identified.

Australia and Poland as comparators

Poland and Australia were specifically chosen as comparators in this study for several reasons. First, traditionally, there is minimal collaboration between Eastern European countries and western countries that have a more advanced level of pharmaceutical care, such as the US, Canada, Australia and New Zealand. A literature review highlighted that the majority of published data investigating pharmacist practice in the NICU originates in the USA, with little to no equivalent or comparative research performed with European countries.⁸ The WHO highlights that transnational collaborative research is important in stimulating the adoption of coherent policies and establishing best practices.¹⁹ Therefore, there is a need to expand research horizons to encompass a more global perspective, to encourage the formation research alliances between nations that are not often highly publicised. This research follows on from previous studies that the authors have performed investigating pharmacist practice in these two countries. A comparison between Australia and Poland was thought to be useful in providing a new and unique perspective on pharmacist practice in NICUs. Due to the variability in NICU pharmacist practice between these two countries, this comparison also enabled a fuller understanding of the range of potential barriers limiting the implementation of standardised practice guidelines and KPIs for pharmacists in this area of practice.

Setting and participants

Purposive, homogenous sampling was used to recruit participants.²⁰ This method was thought to be the most appropriate form of recruitment as it *'focuses on one particular subgroup in which all the sample members are similar, such as a particular occupation or level in an organization's hierarchy.'*²¹ The objectives of the research were specific to the characteristics of the particular group of interest (NICU pharmacists), which was then

subsequently examined in detail.²² Participants were recruited based on the following inclusion criteria:

1. Registered pharmacists, with at least 1 year of hospital pharmacy experience.
2. Practicing within hospitals containing a NICU, providing either direct or indirect pharmaceutical care to the NICU as pharmacist or director of hospital pharmacy.

In this case, indirect pharmacy services refer to dispensary-based roles that include but are not limited to extemporaneous compounding, administrative activities and dispensing. Direct pharmacy services refer to ward-based, patient-direct services including medication chart reviews, therapeutic drug monitoring, counselling of parents etc.

In Poland, clinical pharmacy is not yet well-established in hospital settings, and as such pharmacists do not commonly practice on wards. Therefore, participants in this country were included in the study if they identified as hospital pharmacists who provided some form of pharmaceutical care services (i.e., direct or indirect, as described previously) for the NICU.

Participants were contacted via email through the Paedpharm online pharmacists group and through publicly available registers in Poland, (Register of Facilities delivering Medical Activities [Rejestr Podmiotów Wykonujących Działalność Leczniczą] – RPWDL), and Australia, (Australian and New Zealand Neonatal Network - ANZNN) that identified hospitals with neonatal intensive care units. Paedpharm is an online paediatric pharmacy network that provides pharmacists in Australia and New Zealand a forum to exchange information related to paediatric therapeutics.²³ Furthermore, participants were identified from a previously performed study, involving an online-questionnaire relating to pharmacy services provided in NICUs in Australia and Poland.⁹ At the end of the questionnaire, participants were asked whether they would be interested in participating in further research, involving semi-

structured interviews related to the development of a quality guidance resource for pharmacy practice the NICU. Individuals who voluntarily expressed their interest to participate, were then provided the full study details.

To ensure as minimal as possible disruption for participants, interviews were organized to be conducted at times and locations that were convenient for the participant (i.e. in their workplace), and the researcher (NK) travelled to the participant. In the instance that the distance between the researcher and participant was too great, interviews were conducted over the phone. The researcher (NK) travelled to participants in both countries. Decisions to conduct interviews over the phone were based on the location of the researcher at the time i.e. either in Gdansk, Poland or Sydney, Australia and depended on whether the participant was easily reachable by car or public transport.

Each participant was made aware of the personal goals of the lead researcher in publishing this research as a part of her PhD thesis. The sample size was based on the number of participants targeted to achieve data saturation, and was set at a minimum of 10 participants in each country (10 Australia, 10 Poland).²⁴ Guest et.al. state that for interview studies which “aim to understand common perceptions and experiences among a group of relatively homogeneous individuals, twelve interviews should suffice to attain data saturation and enable the development of meaningful themes and useful interpretations”²⁴.

Data collection

For consistency, each interview was facilitated by one researcher (NK) using a purpose-designed interview guide. The interview guide was adapted from a previous study by Minard et.al. who used focus groups to identify pharmacist perceptions on the implementation of clinical pharmacy KPIs in hospitals in Canada.²⁵ The interview guide comprised six key open-

ended questions, which canvassed the opinions of pharmacists towards the development of a quality measurement tool:

1. What are the guidelines or practice models that you refer to that identify what pharmacist roles or pharmacy services should be performed in the NICU?
2. Which documents contain key performance indicators (KPIs) or quality indicators that are tailored to pharmacist practice and medication management specifically in the NICU?
3. Would you like to see an integrated document comprising a quality guidance resource, which includes a list of clinical pharmacy KPIs specifically tailored for the NICU? Why?
4. What kind of items would you like this resource to contain?
5. What would encourage the use or the implementation of this type of document into the NICU?
6. What are the barriers that you can think of that could oppose its implementation?

The interview guide was pilot-tested for question clarity prior to use. The average interview time was approximately 20 minutes. Field notes were taken during the interviews and each interview was digitally (audio)-recorded and later transcribed verbatim by one researcher (NK). No repeat interviews were carried out as all the relevant information was obtained during each individual interview. Each interview was conducted with participants in their native language i.e. English and Polish. For all interviews that were performed in Polish, the transcripts were translated into English via a tiered process; transcripts were translated from Polish to English by one researcher (NK); these translations were edited and verified by two researchers (IP, BB) to determine whether the language was correct. All transcripts were returned to participants in both Poland and Australia for review and editing. To ensure ease of readability, the qualitative responses of participants are represented by the code 'AP' for

Australian pharmacists and 'PP' for Polish pharmacists.

Data Analysis

The interview transcripts were thematically analysed. Manual inductive coding was used, whereby after transcription, each interview was repeatedly read and the transcript annotated with significant statements from participants responses. Subsequent analysis of these statements led to their categorisation into key themes around the study objectives.²⁶

The information obtained was triangulated through the participation of a team of investigators. Three researchers (NK, BB, IP) independently evaluated the data to ensure the appropriate interpretation of data into descriptive themes in line with the existing questions and study objectives. These initial themes were compared, checked and verified to attain consensus. A pragmatic approach was used to frame the analysis; which allows data to be analysed without the limitations of any specific philosophy.²⁷

RESULTS

Out of the 18 pharmacists in Australia, and 20 pharmacists in Poland invited by the research team, 15 from each country agreed to participate, with a total of 30 interviews taking place. Out of the total group, five participants from Australia, and seven from Poland were participants from a previous study relating to pharmacist practice in the NICU. Thematic saturation appeared to have been achieved with this number of participants in each country, with no new information emerging from interviews, therefore no further sampling was conducted. Participant characteristics are presented in Table 1. The majority of Australian participants identified themselves as NICU pharmacists, and had 1 – 5 years working

experience. In comparison, most Polish pharmacists reported that they were general hospital pharmacists based in the dispensary, and 73.3% had over 10 years work experience.

Three key themes were explored during the interviews held with Australian and Polish participants:

- 1) Lack of guidance in the provision of NICU pharmaceutical care services
- 2) Embracing a pharmacist-specific, quality guidance resource for the NICU
- 3) Constraints limiting the use of quality guidance resource

1) LACK OF GUIDANCE IN THE PROVISION OF NICU PHARMACEUTICAL CARE SERVICES

None of the participants were able to identify any NICU specific quality guidance resources for pharmacists (Table 2). In Australia, pharmacists referred to in-hospital practice standards and training workbooks, however stated that these were all developed by hospitals individually and not shared between sites. Two pharmacists highlighted resources from the pharmacy board as well as state-wide policies, however these were general resources for all hospital pharmacists and were not specific to the NICU.

'I'm not aware of any particular guidelines or practice models for a NICU framework.'

AP3

'We don't have specific NICU KPIs at this point in time.' **AP4**

In comparison, Polish participants highlighted that the only resource available that dictated what roles a pharmacist was to perform was the pharmaceutical legislation, and similarly to Australian responses, comprised a general list of services for all hospital pharmacists and did not define services for the NICU.

'According to the pharmaceutical law, the pharmacist should prepare TPN, cytotoxic medicines (if they are being prescribed) and to participate in clinical research. That is all the law states. It is generalised, not specific to this ward.' **PP14**

'No - everything is generic. There are no indicators that I am aware of, the only ones are those related to oncology wards with chemotherapy... When considering neonatology, I haven't heard of anything like this.' **PP8**

2) EMBRACING A PHARMACIST-SPECIFIC, QUALITY GUIDANCE RESOURCE FOR THE NICU

All Australian participants and 93.3% of Polish participants were open towards the development of a quality guidance resource and felt that this would be useful. The remaining Polish pharmacist, whilst seeing the benefit of such a resource, highlighted that its implementation into the Polish healthcare system would be unsuccessful and unachievable due to the underdeveloped nature of pharmaceutical care in hospitals and did not feel it was relevant for current day practice.

The criteria of this resource varied slightly between countries. Polish pharmacists viewed this resource as more of an introductory framework outlining what clinical services should look like in the NICU, rather than as a quality assessment tool. Respondents highlighted that they were unsure what clinical services to provide to the NICU, as they mostly functioned at a distributive level of practice, and they wanted to have a point of reference clearly outlining what was expected of them. This was viewed as being valuable for pharmacists in order to advance their level of practice and strengthen their clinical roles in ward-based medication management. This type of document was also perceived as an effective means of communicating and asserting to the NICU medical and nursing staff, as well as to hospital management that the pharmacist is a valuable contributor to the therapeutic team. Interestingly, several pharmacists commented that there needed to be a clear distinction

between the role of the doctor and the pharmacist in the NICU, with a definition of what each profession was responsible for so as to not intrude on each other's competencies. Other elements that were proposed included: pharmacist to bed ratios, information on the types of medications used in NICUs as well as examples of commonly encountered medical conditions and their treatment.

'I would be more inclined to view it as a way to strengthen the position of the pharmacist and the role of pharmacist in the treatment process. It also increases knowledge of the role of the pharmacist and what they can do to help improve the general care of the patient comprehensively, from the beginning to the end, taking into account each aspect. I see this document providing highly positive contributions.'

PP2

'Definitely a list of services, definitely how many pharmacists would be needed to service a specific ward. An indication of our legal rights, so what we are able to do and what we are responsible for, and what not to become involved in and what should be left for the doctors and nurses.' **PP14**

Alternatively, as clinical pharmacy is readily practised in Australia, the proposed resource was viewed as having potential as a standard of practice that outlined the niche roles of the pharmacist in the NICU and distinguished pharmacists in this subspecialty from general clinical practice. As such, participants commented that it would be used as a means of maintaining a standardised, quality level of care and also as an accreditation document, proving that these standards were being met. Participants also referred to the inclusion of KPIs in this resource, which were perceived as elements that would allow pharmacists to better prioritise their time

on roles deemed to be important to the quality use of medicines as well as allow the monitoring of pharmacist performance. Furthermore, the proposed quality guidance resource was identified as being a good training kit for new pharmacists coming into this field, needing the inclusion of educational information comprising an overview of the physiology of the neonate, medications used in the NICU and useful resources to refer to.

'I think it would be a good educational tool, not only for pharmacists who have perhaps been doing that role for a long time, but also for newer pharmacists, more junior pharmacists in their career who may need to cover that area or be on call for that area. I think it would be a good tool to document practice and advocate for that subspecialty.' **AP3**

'The SHPA (Society of Hospital Pharmacists Australia) have recommended hours and bed numbers for NICU and special care nurseries... it would be useful to have some recommended tasks and what the key performance indicators should be. Maybe minimum medication safety components as well... it would be good to have recommended texts, minimum texts, minimum standards or minimum guidelines and staffing as well that would be good.' **AP2**

Both Australian and Polish participants highlighted that that they would like this resource to contain a list of pharmaceutical services that should be provided to the NICU to uphold a minimum standard of quality care (Table 3).

'I think a list of pharmaceutical services – this should be outlined, what clinical pharmacists are responsible for.' **PP15**

'I think a breakdown of the role a pharmacist actually has to play in the NICU would be good. Like expectations, I guess of what a pharmacist could contribute to the role.'

AP6

'Its an important component of practice for people to understand what their roles are, but also to give them an insight into aspects of their clinical roles that they might not have necessarily thought about, and aspects of their clinical role that they might not have thought about being able to evaluate.' **AP13**

3) CONSTRAINTS LIMITING THE IMPLEMENTATION OF QUALITY GUIDANCE RESOURCE

Common barriers to the implementation of the proposed resource across both countries included financial constraints, legislative issues, problems associated with the healthcare system and pharmacists possessing the necessary level of neonatal education or training and experience (Table 4).

3.1 FINANCES

Funding was identified as a major barrier in both Australia and Poland to implementing any resource promoting an advanced form of clinical practice on the NICU. Polish participants reported that currently, funding opportunities for the pharmacy department were scarce, resulting in the employment of only a few pharmacists per hospital. The majority of Polish pharmacists recognised that the implementation of the proposed resource would require the engagement of more pharmacists, which the system would simply not be able to afford. Therefore, as a result the limited number of pharmacy staff available at each hospital would also impact upon the uptake of this resource, simply because there are not enough people to do the work required.

'I think first and foremost, there are financial barriers in hiring pharmacists for this position. If pharmacists were to work on the wards, then they would have to hire 4 or 5 times more pharmacists than we already have. Unfortunately, when considering funding, then it is not good.' **PP13**

Similarly, Australian participants referred to financial constraints relating to sourcing funding opportunities specifically for the employment of pharmacists in the NICU to provide the required level of services outlined in the proposed resource. One pharmacist commented that this correlated with the level of value that pharmacy management associated with this service and allocating the relevant funding against other competing resources.

'The ultimate barrier is around management and management's perception around the role and value of pharmacy services in that area. If you tried to summarise that, it is on the one hand funding and the availability of funds to employ pharmacists to provide the level of service.' **AP13**

3.2 EDUCATION AND EXPERIENCE

Pharmacists in both countries also voiced concerns regarding the level of neonatal-based training available to up-skill pharmacists. Some Australian pharmacists commented that neonatal pharmacology was not often offered during pharmacy training programs, and as such there was a perceived lack of awareness and understanding of the medication management processes in this patient population. Pharmacists indicated that this had the potential to limit the implementation of the proposed resource in two ways: pharmacists reluctance in engaging in this field because of the patient group and pharmacists being insufficiently skilled to be able to practice on this ward.

'It's an area where you don't learn at university, how to be a neonatal pharmacist. I would like to see a lot more paediatric and neonatal pharmacology or just awareness in the undergraduate degree, because people are very frightened of getting involved if the patients are so small.' **AP2**

Polish pharmacists voiced concerns relating to foundational-level issues, highlighting their own lack of experience with models of clinical pharmacy. Whilst they expressed a high-level of interest in providing clinical roles, they reported that they did not hold the necessary level of preparation or knowledge in offering such services and were hesitant about the feasibility and possibility of initiating this type of practice.

'...the lack of pharmacist preparation. This is absolutely not spoken about here. There are absolutely no clinical placements, we do not leave the pharmacy and we do not enter the wards. So at the moment, I do not feel at all prepared to fulfil this kind of role.' **PP11**

Furthermore, they credited the current education system as being inadequate in preparing pharmacists for clinical practice. "Clinical pharmacy" was identified as being a certified specialisation within Poland, however participants reported that the Polish pharmacy schools offered this course in a limited capacity, with no practical experience on hospital wards, and the entirety of the course being theory-based. Some pharmacists highlighted that they needed to go externally (overseas) to acquire such training. However, one participant identified that even if this training was sufficient, there is nowhere for pharmacists to practically apply that knowledge in the current system.

'The barriers start at the university level. We are not adequately prepared for this type of practice. Even a specialisation in clinical pharmacy does not prepare us. We have some of the necessary knowledge after we finish this type of specialisation, but

we do not know how to implement it. Not only should our universities prepare us for the work of a clinical pharmacist, but hospitals should also create clinical pharmacist positions. It should be made mandatory that there is a clinical pharmacist employed on all of the hospital wards. This type of practice model would certainly work to satisfy us.' **PP15**

3.3 CURRENT HEALTHCARE SYSTEM

Polish participants identified that the current healthcare practice model functioning in Polish hospitals was a significant barrier to the implementation of a clinical pharmacy-focused resource in the NICU. One pharmacist commented that they did not see clinical pharmacy practice being present in Poland for another 50 years.

'For us it is fascinating to think that maybe, I do not know, in 50 years we will also have a similar system. For the moment, the momentum is not here at all.' **PP5**

The healthcare system was described by participants as being a long-established, traditional, hierarchical structure, whereby doctors and nurses practice on wards, whilst pharmacists are dedicated to the dispensary, managing the supply and preparation of medications. Many participants referred to the practice-culture and mentality of healthcare professionals towards changing pharmacist practice in the NICU. In particular, they expressed to the lack of awareness of doctors and the hospital management around the value and need for the pharmacist to provide ward-based services for neonatal patients.

'For me at this point, if I have to be honest and this is my personal opinion, there is no awareness within the hospital management that the pharmacist may actually contribute to the safety of medications.' **PP1**

'It has to do with the ingrained practice culture. It also depends on how the doctors perceive this model.' **PP7**

'I think above all, the mentality and the long-established procedures, as well as the inter-professional relationship between the doctor and the pharmacist, which in Poland simply does not function. This is the main barrier.' **PP11**

It is apparent that there is no incentive within the Polish healthcare system to modify the current pharmacy practice model as it is perceived that the level of care being provided to neonates is satisfactory, and the professional roles allocated to doctors, nurses and pharmacists are being fulfilled. Furthermore, participants reported that hospital pharmacists are not well reimbursed for their services, and therefore there is reluctance to perform additional roles for minimal reward.

'... I must say that our level of care is good because we have good results when it comes to treating these children. The care is not bad, but I think it would be even better if there was a pharmacist involved.' **PP3**

3.4 LEGISLATION

Only Polish participants drew attention to the fact that there is no appropriate pharmaceutical legislation authorising pharmacist involvement on the ward. This was identified as a significant

issue, as the this 'permission' was perceived as essential in giving pharmacists the power to make pharmacotherapy-related decisions and become involved in patient care in the NICU. Furthermore, pharmacists highlighted that there was no regulation in the law that specified pharmacist to bed ratios. This was also deemed to be important, due to the current staff shortages in hospitals, which are seen to impact upon the ability of the pharmacy department to provide services.

'I will begin by saying that our pharmaceutical law does not state that the pharmacist is allowed to enter any ward. Of course a hospital director or someone who manages a hospital may authorise this, but if it is not written in the law we are unsure what the pharmacist should be there for what they are responsible for and what role they play.' **PP3**

Interestingly, only one pharmacist recognised that the laws did not say that a pharmacist could not be in a ward.

'I am not sure if the legislation prevents us from accessing it. In my opinion it is not properly regulated. It is simply not specified that we are able to have access. No-one took this under consideration, that is why the pharmacist is not present on the ward.'

PP4

3.5 SUPPORT FROM PROFESSIONAL PHARMACY BODIES

Interestingly, only pharmacists from Australia identified that in order for the proposed resource to be considered by NICU practice settings, it would need the acceptance and support of a national pharmacy body or neonatal organisation. Without this, participants felt that the hospital management would not support greater pharmacist involvement in this

ward. Furthermore, participants highlighted that where practice is established, both pharmacists and doctors may be reluctant to change and adapt to a new system. From a personal perspective, pharmacists recognised increased workload as a barrier to the implementation process, mainly due to the time needed to dedicate to fulfilling the standards outlined in the tool.

'You'd have to have appropriate stakeholder engagement. So you would have to either have the document prepared, and then a professional organisation support it. So I would think you would need to get it endorsed either by the SHPA and the other option that I think would be quite appropriate is if the SHPA acted as a advocate through the ANZNN (Australian and New Zealand Neonatal Network), so you would want that to be a jointly endorsed from both of those professional bodies for it to be effective I would think.' **AP10**

'People not being willing to change practice or measure practice. Time constraints as well. A lot of times, the NICU is co-allocated with another role so obviously you have only a certain amount of time that you can spend on it, so you may not be able to adhere to the guidelines.' **AP4**

DISCUSSION

To our knowledge, this is the first qualitative study to explore pharmacist opinions towards the development of a quality measurement tool specifically for clinical pharmacy practice in the NICU. This qualitative research is valuable as it provides an initial insight into understanding the needs of NICU pharmacists and assessing whether there is a demand for quality guidance resources to be made available for sub-specialties of pharmacy practice.

One concept arising from the study that warrants discussion is that pharmacists in both Australia and Poland identified a lack of NICU clinical pharmacy guidelines and a subsequent

lack of professional guidance to practicing within this setting. As such, the findings from this study draw attention to a significant gap in practice. The provision of pharmaceutical care services in NICUs in both Australia and Poland are based on each hospital settings' individual and varied interpretations of the concept of 'good pharmacy practice', without the guidance of a minimum standard of practice. As a result, there is potential for differences in the level of pharmacy services delivered to NICU settings between these two countries. It is not known what impact these variances have upon patient outcomes or the rational use of resources. However, despite these differences in practice, both Australian and Polish participants in this research perceived a need for the development of a quality or guidance tool to standardise pharmacy practice in the NICU at least on a local and national level. This finding is reinforced by the International Pharmaceutical Federation (FIP), who highlight that national standards, depicting good pharmacy practice and comprising a quality management framework, should be set by pharmacy organisations.¹³ The FIP recognise that pharmacy practice may vary in settings between and within countries, however state that a 'baseline' should be established that outlines the minimum level of quality practice.¹³ However, to date there have not been any guidance documents or performance measures established for neonatal pharmacists. Furthermore, there are no standardised measures facilitating the benchmarking of pharmacy services between settings nationally and internationally. Ng et.al. report that in a resource-scare environment, clinical governance demands that clinical pharmacy, in accordance with other clinical health services, must demonstrate the value of its contribution to patient care.¹⁸ They highlight that without the availability of key performance indicators or quality measures, pharmacists are unable to justify in a quantitative and robust manner their contributions to patient care.¹⁸ This is of particular significance to the Polish setting, when considering the current issues within the health-care system that limit the implementation of clinical pharmacy practice.

When considering the barriers identified by participants towards the implementation of a quality guidance resource, some of our findings were consistent with other research dedicated to identifying challenges affecting the engagement of clinical pharmacy key performance indicators (cpKPIs) in the hospital setting.²⁵ Minard et.al. reported barriers comprised of environmental constraints, relating to inconsistent staffing levels, funding or resources, as well as work burden issues.²⁵ Another study by Mekonnen et.al. investigating the implementation of new medication safety programs in Ethiopian hospitals mandated by updated minimum practice guidelines, highlighted a significant barrier as a lack of pharmacist knowledge and skills necessary for the performance of clinical services required by the guidelines.²⁸ This barrier in particular is similar to that expressed by Polish participants, and their unfamiliarity with the direct provision of ward-based, clinical services potentially outlined in the quality resource. The barriers identified in this research outnumbered the perceived benefits to the quality guidance resource, and varied between Australia and Poland. The differences observed in the participant responses between the two countries may be attributed to the numerous variations in healthcare systems, including legislation, funding and education. However, it is apparent that practice culture is a significant influencing factor. Overall, Polish participants were more conservative and expressed concerns relating to the current hospital hierarchy i.e. maintaining the status quo. Polish interviewees often focused on the lack of legislation in specifying that a pharmacist was able to participate in ward-based medication management. These findings are similar to those presented by Pawłowska et.al. who highlighted that the majority of Polish hospital pharmacists surveyed felt that significant changes to legislation were necessary to improve hospital pharmacy practice.²⁹ However, only one pharmacist acknowledged that it may be more of a case that the law does not specifically state that pharmacists are not permitted to practice on the ward. As such, this raises the question as to whether Polish pharmacists are actually receptive to practice changes. In comparison, Australian pharmacists seemed to be

more engaged and proactive in their practice, and were willing to further advance service provision to this ward to permit the standardisation of practice. As such, these diverse attitudes may have varying impact on pharmacists willingness and motivation to adapt to a different model of practice.

It is important to note that pharmacists from both countries readily highlighted the potential benefits to the implementation of a quality resource, including allowing pharmacists a full understanding of the roles needed to be undertaken in this setting, improving the standardisation of care, as well as and strengthening pharmacist positions on the NICU, particularly in reference to their standing among other members of the multidisciplinary treating team. These findings are similar to those obtained by Minard et.al., who explored the perceived barriers and facilitators towards the use of cpKPIs in general hospital settings in Canada.²⁵ They highlight that pharmacists perceived the implementation of cpKPIs would improve consistency in pharmacy practice, help align the expectations of other healthcare professionals and allow pharmacists a clear focus of roles and services that need to be performed.²⁵

The findings of this study emphasise that there is a lack of pharmacist support and guidance in both Australia and Poland relating to practice in the NICU. There is an opportunity for future research to address this gap in knowledge, and potentially develop quality measures tailored specifically to this patient population that could be adapted to each practice setting. As this is a specialised area of practice, with only limited numbers of neonatal beds in each country, a standardised quality tool may in fact help the benchmarking of clinical pharmacy services on a national scale and promote a more co-ordinated approach to advancing pharmaceutical care providing to this high-risk patient population. By assessing pharmacist perspectives towards the implementation of a quality resource, as well as the perceived barriers limiting its use, these findings are an important step in the knowledge-to-action

process and may be useful in future research in the selection and development of interventions for both Australia and Poland.

LIMITATIONS

The sample size used in this study was small, and as such the opinions expressed may not be representative of all pharmacists in Australia and Poland. In addition, due to the voluntary nature of participation in interviews, there is a possibility that pharmacists who participated may have different views to those who chose not to volunteer. Sampling bias may be associated with participants who were recruited from the previous study. The sample of participants from each country were non-equivalent in terms of their personal characteristics (i.e., practice experience, educational background, position in hospital). Therefore, the results may, to some extent, reflect those differences in addition to country-specific differences.

There is potential for researcher bias in interpreting the responses from participants. This has sought to be minimized by ensuring three individual analyses of the data by three separate researchers. The themes that achieved consensus were then combined to form the final results.

Furthermore, the interviews were transcribed and translated by one researcher, and any errors that were made may not have been picked up in the analyses performed by the other researchers.

CONCLUSION

Although there are significant differences in the type of pharmacist practice systems functioning in each country, pharmacists in both Australia and Poland demonstrated significant support for the development of a quality measurement tool to guide and structure practice in the NICU, and recognised benefits to its implementation. Future efforts should be directed at standardising pharmacy practice in NICUs through the development of quality measures, including practice standards and key performance indicators that can be adapted to different practice settings, both on a national and international scale.

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TABLE 1 – DEMOGRAPHICS

	AUSTRALIA (%)	POLAND (%)
<u>NUMBER OF RESPONDENTS</u>	15	15
<u>GENDER OF RESPONDENTS</u>		
FEMALE	11 (73.3)	14 (93.3)
<u>QUALIFICATIONS</u>		
BACHELORS DEGREE	4 (26.7)	0
MASTERS DEGREE	7 (46.7)	14 (93.3)
PHD DEGREE	1 (6.7)	1 (6.7)
POST-GRADUATE CERTIFICATE/DIPLOMA	3 (20)	0
<u>SPECIALISED QUALIFICATIONS/TRAINING</u>		
YES	1 (6.7)	2 (13.3)
CENTRALIZED INTRAVENOUS ADDITIVE SERVICES (CIVAS)/ TOTAL PARENTERAL NUTRITION (TPN) PHARMACIST	1 (6.7)	0
CLINICAL PHARMACY	0	2 (13.3)
NO	14 (93.3)	13 (86.7)
<u>POSITION IN THE HOSPITAL</u>		
NICU PHARMACIST	10 (66.7)	0
DIRECTOR OF PHARMACY	3 (20)	4 (26.7)
PHARMACIST WORKING IN MAIN HOSPITAL PHARMACY		11 (73.3)
OTHER		
DEPUTY DIRECTOR	1 (6.7)	0
SPECIALIST WOMEN, YOUTH AND CHILDREN PHARMACIST	1 (6.7)	0
<u>EXPERIENCE</u>		
< 1 YEAR	2 (13.3)	0
BETWEEN 1-5 YEARS	9 (60)	0
BETWEEN 6-10 YEARS	2 (13.3)	4 (26.7)

> 10 YEARS	2 (13.3)	11 (73.3)
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TABLE 2 – PHARMACIST PERCEPTIONS

	AUSTRALIA N = 15 (%)	POLAND N = 15 (%)
ARE THERE ANY GUIDELINES/PRACTICE MODELS/KEY PERFORMANCE INDICATORS (KPI'S)/QUALITY INDICATORS THAT YOU ARE AWARE OF THAT PHARMACISTS CAN USE TO GUIDE THEIR MEDICATION MANAGEMENT SPECIFICALLY IN THE NICU?		
YES	0	0
NO	14 (93.3)	12 (80)
UNSURE	1 (6.7)	3 (20)
WOULD YOU LIKE TO SEE AN INTEGRATED DOCUMENT COMPRISING AN IDEAL PRACTICE MODEL, WHICH INCLUDES A LIST OF CLINICAL PHARMACY KPI'S SPECIFICALLY TAILORED FOR THE NICU?		
YES	15 (100)	14 (93.3)
NOT ACHIEVABLE WITH CURRENT SYSTEM	0	1 (6.7)
DO YOU BELIEVE THAT THE CURRENT MODEL OF PHARMACEUTICAL CARE PRACTICE IN YOUR COUNTRY WORKS AND MEETS THE NEEDS OF NICU PATIENTS?		
YES	13 (86.7)	3 (20)
NO	1 (6.7)	11 (73.3)
UNSURE	1 (6.7)	1 (6.7)

TABLE 3 - WHAT SHOULD A QUALITY GUIDANCE RESOURCE CONTAIN?

POLAND	AUSTRALIA
<p><i>'...what it means to be a pharmacist working on this ward, with a list of activities that a pharmacist would have to fulfil. A scope of practice. Also the relevant legislation and responsibilities – I believe that this should be defined in detail.'</i> PP1</p> <p><i>'For sure, something would have to be written that highlights the scope of our responsibilities, what we can do, and what they will ask us. In the sense that examples should be provided of dosing for certain indications. The scope of our responsibilities, whether we are only able to advise or are we responsible for this service, and who signs off on this service. Well, it would be good if there was some sort of guideline prepared by pharmacists relating to the administration of medicines, because on the ward they have their own standards (where to administer, how much and how).'</i> PP5</p> <p><i>'I definitely think a list of pharmaceutical services, because a pharmacist who would have to practice on this ward would have to know what they are responsible for. You would have to define the role of the pharmacist and the role of the doctor so that there is no confusion. There would also have to be a ratio of how many pharmacists per beds, because without this I think the hospital management is likely to take short-cuts, and having a single pharmacist on the ward might exhaust them.'</i> PP6</p> <p><i>'I would want some information on what medications are used on this ward, and then it would possibly be easier for us to identify relevant literature that would be useful... Some standards of conduct for the neonatal ward, or what to do in difficult situations which are not covered by the existing standards.'</i> PP11</p> <p><i>'It would be great if it included the roles of the pharmacist and I think it would be easier for us and for the nurses and doctors to understand what we do. Because they would see that these are our duties, this is what we do and I think there would finally be some sort of</i></p>	<p><i>'Some specific recommendations around therapeutic drug monitoring in the NICU... what should be specific around these guidelines is the differences between the services in a neonatal unit and a more general intensive care unit or a general or paediatric unit. And so its highlighting what sort of differences pharmacist who are providing services in the NICU need to be aware of and cognisant of for the babies.'</i> AP1</p> <p><i>'I think it should be written by NICU pharmacists who know the business, who have been working there for a while, and should include perhaps things like, recommended reading for people new to the area. It should include information on the conditions the patients have, information on current and up-to-date treatments, medications... It should include those KPI's that should give guidance to help those experienced NICU pharmacists, junior NICU pharmacists and also the people who manage them to know what they do. If they are supposed to go in there 40 hours a week, what are they supposed to be doing, how do we know if they are doing the right thing? I think it demonstrates to management, to the executive at the hospital, to medical staff and to nursing staff that this is why we are doing what we are doing.'</i> AP3</p> <p><i>'Minimum required services for certain levels of care. Like a competency assessment model that contains what the requirements are, what are the competencies that should be met for those standards. That would be useful. KPIs that are within that as well that should be monitored.'</i> AP10</p> <p><i>'I think it would be really good to have basics regarding the infant in the neonate. So looking at their care, what problems that you would see, just basic – these are the air-pressures that you would see in a</i></p>

<p><i>organisation. There would be greater control over what happens on the ward.'</i> PP12</p>	<p><i>neonate, this is what you are likely to see in terms of their lines and what's going on with their lung functions and those things. And then where the medication fits in there. And then what is expected for you to look around that.'</i> AP11</p> <p><i>'I suppose if you use something like the SHPA (Society of Hospital Pharmacists Australia) standards of practice as a model document, I think that does include aspects around the core components. The only other aspect is around training and education resources. There is a lot of interest around up-skilling staff, so its one thing to tell people this is what you should be doing but they need to have the skills to be able to interpret what they are looking at. This is extremely important in the neonatal setting, some of the drugs they might not have seen before, that type of thing.'</i> AP13</p>
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TABLE 4 – BARRIERS TO IMPLEMENTING QUALITY GUIDANCE DOCUMENT

POLAND	AUSTRALIA
FINANCES	
<p><i>‘Everything is dependent on the employment of people and the number of employees. Considering the model that we currently use to provide pharmaceutical services, we would not have enough people to be able to cope with it all. This is strictly related to health care financing, whereby the national health fund reimburses specific services.’ PP2</i></p> <p><i>‘The fundamental barrier is a small number of staff. This is a fundamental barrier, without additional personnel we will not be able to overcome it - 700 beds, 6 people - that is one person per 100 beds. How? And this is not just monitoring the ward, but also the administrative duties, tenders, and other such things that take up a lot of time because some things are only able to be done and signed off by the pharmacist. There is not enough of us to even check the work of the technicians.’ PP5</i></p> <p><i>‘Financial barriers. When anyone wants to introduce new changes, this is the first barrier that they face, maybe not the first, but one of the first questions is ‘how much will this cost?’. Obviously, for this to work you need people, pharmacists, and for that you need money. So I think that the financial barrier is present, because when you look at a personnel barrier, sooner or later people will be convinced that it works when they see its positive effects. On the other hand, this financial barrier is apparent, and I think it is big.’ PP6</i></p>	<p><i>‘I guess the obvious one is resourcing. There are different levels of resources in different hospitals across Australia and its sometimes a bit of a struggle to get through the workload, but I think guidance documents such as these should help. Both in informing current practice and in future planning.’ AP1</i></p> <p><i>‘Financial, if you’ve got competing resources. Financial is going to be one of them.’ AP3</i></p> <p><i>‘I think both financial resources and additional staff are drivers for any kind of service. And like I said before, I think that provided that it was evidence-based and up-to-date then I think that would probably be the other driver.’ AP6</i></p>
EDUCATION AND EXPERIENCE	
<p><i>‘One barrier is definitely our education system. The system of educating pharmacists and doctors would have to change. This issue is not independent of doctors. I think this is an important barrier.’ PP7</i></p> <p><i>‘Our model of education in Poland does not prepare us for practice in a clinical capacity, or on the ward. Above all, education. Our level of education is directed at a different type of practice, something other than actual ward-based practice with the patient.’ PP9</i></p>	<p><i>‘...what we learn in the NICU is obviously what we have been trained for by the pharmacists. But it is not something that is focused on in terms of in your pre-registration year when you are an intern, no-one really looks at NICU. I know that it is quite specific and there isn’t that many NICU beds, but it is not something that is ever touched on. You don’t learn it in your degree and you don’t learn it when you are an intern, unless you are actually exposed to it. Even in our hospital, we have the pharmacists that cover the nursery but we</i></p>

<p><i>'...the lack of pharmacist preparation. This is absolutely not spoken about here. There are absolutely no clinical placements, we do not leave the pharmacy and we do not enter the wards. So at the moment, I do not feel at all prepared to fulfil this kind of role.'</i> PP11</p>	<p><i>don't really have the interns covering them because fear that there is too much of a high risk. So you don't really get that exposure until you actually need to do it, and by then it might be a little bit too late.'</i> AP11</p>
<p>CURRENT HEALTH CARE SYSTEM</p>	<p>SUPPORT FROM PROFESSIONAL PHARMACY BODY AND OTHER PROFESSIONAL STAFF</p>
<p><i>'We have a problem, and I will continue to point out that the pharmacist is not valued. This kind of research that you are undertaking demonstrates that it is necessary to realise that the pharmacist can perform certain tasks and support the doctor on the ward.'</i> PP1</p> <p><i>'Under these conditions, I think it would be difficult. That is why, from what I see, there is no such option for the pharmacist to become closer to the ward. I think it would be an issue for the doctors. Not for the pharmacist, I think they would adapt quickly. Because they would understand what their duties are, but it would be more difficult to communicate to the medical community that there is someone else present who has insight into similar things and who can make decisions on similar matters. So, I believe there would be resistance and a lack of trust for the pharmacist.'</i> PP4</p> <p><i>'The barriers that we have here are that people are not very willing to change.'</i> PP4</p>	<p><i>'It would have to be accepted and supported by some large national body, for a hospital service to make sure that its introduced. So if you had SHPA support, or children's health Australasia support, something like along those lines, or even the Australian Commission on Safety and Quality in Healthcare, someone like that to ratify it, then you'd be more likely to get the hospital to accept it.'</i> AP2</p> <p><i>'... support from the NICU executives as well as support from pharmacy management. If you were reporting KPIs, some sort of support from a national or state body like we would do with other med safety indicators.'</i> AP7</p> <p><i>'Unless it had some official status or standing or a body that came out to say this is our expectation or standard of practice for pharmacy within neonatology it would be unlikely to gather enough weight... I guess resources and support. Whoever your neonatal director is, in terms of your NICU, they need to support having a pharmacist in there. If you don't have that support within the clinical unit, whether its doctors and nursing, but particularly the lead clinicians, then it will never move. You also need support from the head of the pharmacy department to say this is a good use of resources. And then you need to get the executives on board to say here's some money to make this happen.'</i> AP9</p>
<p>LEGISLATION</p>	
<p><i>'First of all, the legal regulations do not specify what is an appropriate number of pharmacists to be employed. There are pharmaceutical laws that define the role that a pharmacist should fulfil and within that it is specified that they should provide medication information, and that's it... The law does not support us, does not have a</i></p>	

standard that states how many pharmacists per bed. It is only starting to be fought for now. Previously, there used to be one pharmacist per 100 beds. That was a couple of years ago. Now there is no norm... Also, the truth is that professional duties are often done by technicians and not qualified pharmacists, who should be doing it, and no-one has time to even just look into the ward or talk to the doctor. There is no support system that would allow this.'

PP5