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A COST-ANALYSIS OF OUTPATIENT PAEDIATRIC PENICILLIN ALLERGY DE-LABELLING USING TELEMEDICINE

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KEYWORDS

Anaphylaxis; Beta-lactam; Children; Cost-Analysis; Drug Allergy; Paediatric; Penicillin; Telemedicine

Abbreviations

GP	General Practitioner
NCHD	Non-Consultant Hospital Doctor
OPD	Outpatient Department

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To the Editor

Penicillin allergy is reported in up to 5% of children and 10% of the general population [1,2]. More than 90% of labelled children are confirmed non-allergic on testing [3]. Spurious penicillin-allergy labelling negatively influences healthcare outcomes with significant health and cost implications [2,4].

The recent Covid-19 pandemic has resulted in significant changes in the delivery of healthcare, with focus shifted to telemedicine. We previously reported on the use of telemedicine and outpatient (OPD) oral challenges as a pragmatic approach to de-labelling low probability penicillin allergic children with high parental satisfaction [1]. In this study, children considered low probability of true penicillin allergy, as defined by non-immediate symptoms of an allergic reaction (mainly skin rash) and absence of systemic/severe symptoms or poorly controlled asthma, were recruited and de-labelled over a 7-month period. It is likely that telemedicine will continue to be of value in the aftermath of Covid-19 as hospital services come under pressure and social distancing is required particularly among vulnerable patients. Due consideration should also be given to more cost-effective use of current resources by clinicians in this post-Covid era.

The aim of this manuscript is to report on a preliminary comparison of the direct cost of implementing the telemedicine study intervention [1] versus existing, standardised local practice. Ethical approval was obtained from the University Hospital Galway clinical research ethics committee (Ref. C.A.2020). All parents / patients provided written informed consent.

Established practice in our hospital (in common with many secondary/tertiary hospitals) is an outpatient visit for doctor assessment of penicillin allergy followed by day ward admission for nurse-led graded oral drug challenge (4 hours - graded doses of antibiotic over 2 hours reaching an age-appropriate total dose, followed by 2 hours supervision) and 5-day home antibiotic course. The study intervention [1] undertook initial telemedicine consultation in order to screen patients for low probability of allergy (replacing the outpatient visit), followed by single dose oral challenge in an outpatient setting (2 hours – single age-appropriate dose of antibiotic followed by 2 hours supervision) and 5-day home antibiotic course. The study intervention de-labelled up to 9 children in a 4-hour clinic, requiring only the use of a single room. Children sat in the outpatient waiting room for the duration of the 2-hour observation period. Established practice de-labelled one child per day due to demand on day ward beds.

Cost-analysis considered the staffing requirements and estimated staff time required to undertake each step of the process are outlined in Tables 1-2. Consultant supervision and clerical officer for initial patient check-in (2.5 minutes) was required in both protocols. Established practice involved Non-Consultant Hospital Doctor (NCHD)-led outpatient face-to-face consultation (30 minutes); nurse-led oral challenge (270 minutes); a day ward bed; nurse-led follow-up phone call (15 minutes); nurse-organised General Practitioner (GP) correspondence to report challenge outcome (15 minutes), dictated by the NCHD (15 minutes) and typed by the department clerical

officer (15 minutes). Study intervention involved clerical officer contacting patients to schedule telemedicine appointments (15 minutes); NCHD-led teleconsultation (30 minutes); NCHD-led oral challenge (150 minutes); outpatient oral challenge; NCHD-led follow-up phone call (15 minutes) and dictation of GP correspondence (15 minutes), typed by the department clerical officer (15 minutes).

A cost-analysis, from a healthcare perspective, was conducted to estimate and compare the direct implementation costs of the study intervention and existing standard practice. As described by Polsky and Glick (2009) [5], this process involved identifying, measuring and valuing the healthcare resources involved in the delivery of both strategies in the hospital and outpatient settings in Ireland. Unit costs, in 2019 € prices, were identified from publicly available data sources including the Irish health service published salaries of clinicians/clerical staff (Table 1-2) [6,7,8] Where necessary, unit costs were inflated to 2019 prices using the Irish Central Statistics Office medical inflation index. It is acknowledged that these figures represent an estimation of the direct implementation costs only and do not take into consideration a range of direct and indirect costs. In practice, resource use data was prospectively collected alongside the pilot study. In cases where such data were not recorded directly, expert opinion extracted retrospectively from participating clinicians was used to estimate resource use. In terms of unit costs, salary costs were estimated on the basis of the relevant Health Service Executive salary scales and following Irish health economic guidance (HIQA, 2019). The relevant staff positions considered for the purposes of salary scales were a Consultant Type B (€174651 per annum), Registrar (NCHD) (€56850 per annum), Staff Nurse (€29860 per annum), and Clerical Officer Grade (€23999 per annum). Hospital related costs (outpatient visit and day ward visit cost) were estimated based on published data from the Hospital Pricing Office in Ireland.

Tables 1-2 outline a comparison of the cost-analysis of established standard practice and the study intervention. The cost-analysis estimated that standard practice for de-labelling paediatric penicillin allergy amounted to €1342.96 per patient (Table 1). This compared to €518.36 per patient in the study intervention (Table 2). At secondary care level in Ireland, the estimated current cost of an outpatient visit is approximately €134.36 and a day ward bed approximately €672 per patient [6,7]. The study outpatient visit was longer than an average outpatient visit and so is likely more expensive than the average cost of €134.36. However, the financial cost of performing a de-labelling procedure using this novel approach would still substantially reduce, as a day ward bed would not be necessary.

The study intervention de-labelled 99 children, at an estimated total cost of €51,318 compared with an estimated total cost €132,953 if established practice had been adopted in this cohort. Of the 99 children de-labelled, 78 were successfully contacted for follow up one year later.

Reassuringly, 36/78 patients have confirmed use of Penicillin since de-labelling and 75/78 parents reported confidence to use penicillin in the future, if required [9].

In a time of unprecedented change, due consideration to the delivery of healthcare is required necessitating a review of current practices and innovation in the future delivery of these services, mindful of patient need, satisfaction, clinical standards and cost-effectiveness.

A recent systematic review confirms increased inpatient costs associated with having a penicillin allergy label [10]. In the original study [1], 87% of the initial cohort were considered low probability of allergy; further evidence that most children labelled penicillin-allergic are suitable for this cost-saving de-labelling strategy. Consideration must be given to the use of valuable allergy services and associated costs undertaking de-labelling procedures if parents continue to avoid penicillin. Follow up confirms subsequent use of penicillin in this cohort indicating that de-labelling is worthwhile [9], particularly as inappropriate labelling often persists into adulthood.

Our study supports the use of telemedicine for direct consultation with parents as a useful screening tool for risk stratification and decision making in drug allergy management in children, thus optimising the subsequent use of healthcare resources, which is even more relevant now in the presence of Covid-19. It is conceivable that low probability penicillin challenges can be carried out in primary care, and potentially in patients' homes with input from healthcare professionals through telemedicine [1]. A further cost-saving approach to be considered is adopting this pragmatic model as a nurse-led procedure entirely, particularly given that there is little risk of serious reaction in this low probability cohort [1,3].

It is important to note that our study was limited to the analysis of direct implementation costs only and did not consider follow-on cost implications elsewhere, within and outside of the healthcare system. That is, de-labelling children would have follow on impacts on their healthcare service usage and costs over the remainder of their lifetimes. Furthermore, it would have implications for indirect costs, such as out-of-pocket expenses. Further research is required to estimate the nature of these impacts which fall on healthcare budgets, patients and their families.

This study provides only a pragmatic direct cost comparison assessment. Further elements should be taken into account for detailed cost-effectiveness analysis including patient/parent-reported outcomes, indirect costs (e.g. loss of parental working time, travel) and long term clinical and cost implications of de-labelling (such as antibiotic expenditure, complications of treatment).

Most paediatric penicillin allergy labelled cases are false with associated negative individual and public health consequences [2,3]. This study presents a cost saving approach to de-labelling penicillin allergy in children, using telemedicine and outpatient resources for low probability cases. We propose that this novel pragmatic model is particularly relevant in the presence of Covid-19. Future studies are required to consider other cost-saving approaches including replication of this model in primary care or as an entirely nurse-led procedure.

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Table 1: Established procedure: Day Ward paediatric penicillin de-labelling protocol

Resource Category	Resource Item	Unit/measure	Unit cost (€) in 2019 prices	Source
1. Initial OPD visit (30 minutes)	- Consultant Supervision - NCHD time - Nursing time - Clerical Officer time - OPD Visit	- Per patient - Per patient - Per patient 2.5 minutes - Per patient	43 14 7.4 0.5 134.36	https://www.hse.ie/eng/staff/resources/hr-circulars/hr-circular-020-2019-appendix-3-salary-scales-1-september-2019.pdf [8] - Health Services Executive, Ireland 2013. <i>Ready Reckoner 2013. Ready reckoner of acute hospital inpatient and day case activity & costs (summarised by DRG) relating to 2011 costs and activity.</i> 2013. [6]

2. Oral Challenge (270 mins - 30 minutes consult + 240 minutes challenge)	• Consultant Supervision • Nursing time • Clerical Officer time • Day Ward Bed visit	• Per patient • Per patient • 2.5 minutes • Per patient	• 387.5 • 66.3 • 0.5 • 672	• https://www.hse.ie/eng/staff/resources/hr-circulars/hr-circular-020-2019-appendix-3-salary-scales-1-september-2019.pdf [8] • Health Services Executive, Ireland 2019. <i>Healthcare Pricing Office. ABF 2019. Admitted patient price list. DRG prices for inpatient and day cases 2019.</i> Available from: http://www.hpo.ie/abf/ABF2019AdmittedPatientPriceList.pdf [7]
3. Follow up Telephone Consultation (15 minutes)	• Nursing time	• Per patient	• 3.7	• https://www.hse.ie/eng/staff/resources/hr-circulars/hr-circular-020-2019-appendix-3-salary-scales-1-september-2019.pdf [8]
4. Follow up letter to GP (15 minutes)	• NCHD time • Nursing time • Clerical Officer time	• Per patient • Per patient • Per patient	• 7 • 3.7 • 3	• https://www.hse.ie/eng/staff/resources/hr-circulars/hr-circular-020-2019-appendix-3-salary-scales-1-september-2019.pdf [8]
Total Cost		• Per patient	1342.96	

Table 2: Study intervention: Outpatient paediatric penicillin de-labelling protocol

Resource Category	Resource Item	Unit/measure	Unit cost (€) in 2019 prices	Source
1. Telephone screening consultation (30 minutes)	- Consultant Supervision - NCHD time - Clerical Officer time scheduling appointment	- Per patient - Per patient 15 minutes	43 14 3	https://www.hse.ie/eng/staff/resources/hr-circulars/hr-circular-020-2019-appendix-3-salary-scales-1-september-2019.pdf (8)
2. Oral Challenge (150 minutes – 30 minutes consult + 120 minutes challenge)	- Consultant Supervision - NCHD time - Clerical Officer time - OPD visit	- Per patient - Per patient 2.5 minutes - Per patient	215 70 0.5 134.36	https://www.hse.ie/eng/staff/resources/hr-circulars/hr-circular-020-2019-appendix-3-salary-scales-1-september-2019.pdf (8) - Health Services Executive, Ireland 2013. <i>Ready Reckoner 2013. Ready reckoner of acute hospital inpatient and day case activity & costs (summarised by DRG) relating to 2011 costs and activity.</i> 2013. (6)
3. Follow up Telephone Consultation (15 minutes)	- Consultant Supervision - NCHD time	- Per patient - Per patient	21.5 7	https://www.hse.ie/eng/staff/resources/hr-circulars/hr-circular-020-2019-appendix-3-salary-scales-1-september-2019.pdf (8)

4. Follow up letter to GP (15 minutes)	- NCHD time - Clerical Officer time	- Per patient 15 minutes	7 3	https://www.hse.ie/eng/staff/resources/hr-circulars/hr-circular-020-2019-appendix-3-salary-scales-1-september-2019.pdf (8)
Total Cost		Per patient	518.36	