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Data collection in the Collaborative Wilms Tumour Africa Project

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1. Introduction

Data matters. Carefully collected and documented evidence gives confidence to clinical management, is essential for the planning of future health needs and forms the basis of a cancer registry. Data are the foundation on which protocols, prognostications, follow up and supportive care are based; and data are only relevant if appropriate to the children from the settings where the data are collected. Evidence is also helpful in international collaborations to inform others who have not worked in a similar setting. Proper data is essential for adequate resource mobilization and distribution. (see Figs. 1–5).

All clinical trials require careful documentation and can help improve the care of children with cancer, including in sub-Saharan Africa [1]. The Collaborative Wilms Tumour Africa Project is implementing a consensus-adapted treatment guideline as a prospective clinical trial with uniform outcome evaluation. This is being undertaken in eight centres in Malawi, Cameroon, Ghana, Zimbabwe and Ethiopia. Enrolment started in 2014. The project is funded by World Child Cancer and the International Society of Pediatric Oncology (SIOP). The overall aim is to increase survival to more than 50% and to decrease both abandonment of treatment and death during treatment to less than 10%. To understand and thereby reduce deaths and decrease abandonment requires careful and detailed documentation of the problems faced by families and children with cancer in the setting in which the children are treated. This project is collecting hospital-based data which can answer questions about patient presentation to hospital and outcomes of treatment. Population-based cancer registration is necessary to understand the prevalence of cancers. Knowing how common a cancer is would help us understand the lack or otherwise failure of access to care. Unfortunately these registers are very limited in sub-Saharan Africa.

We aim to achieve improved, long-term results by giving priority to interventions with most impact on childhood cancer care and survival. Local teams decide on which interventions to prioritise and how to assess feasibility. We try to keep things as simple as possible and to do 'simple things' well. Additionally, we realize we can only improve and implement interventions step by step. We applied these same 'principles' when developing and implementing the data collection and management structure. Our systems for data collection and data entry are simple but could be improved. Data entry has to be checked centrally as double entry cannot be done locally and data are transferred in a password controlled dropbox. Improvements are possible in data monitoring, control and electronic data entry; all require funding.

In March 2013, at the beginning of the collaborative project, a three-day work meeting was held in Blantyre, Malawi. Team leaders and the principal co-ordinator attended from Cameroon, Accra (Ghana), Blantyre (Malawi) and Kampala (Uganda). Together, we developed the treatment guideline, defined locally relevant clinical questions and designed the case registration forms (CRFs). Each individual item on the CRF was checked to decide whether it should be included, and conclusions were by consensus agreement.

As a draft template we used the case record form of the SIOP renal tumour study group that had been modified (simplified) for use in Malawi. Pathologists and surgeons from each local centre were asked to modify their sections as they saw fit. For example, at the surgeons' suggestion, the surgical section starts with a simple question: 'At operation does it look like a Wilms tumour: yes/no, if

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Fig. 1. Archive of medical files in Blantyre, Malawi.

Fig. 2. The person is more important than the system - Dalida Pidini, data manager in Blantyre, Malawi.

no – please specify'.

We sometimes had to find a good compromise. For example, we wanted to document the size of the tumour at diagnosis and after preoperative chemotherapy to assess the response. It was expected that imaging techniques (ultrasonography, CT scan or MRI) with reliable measurement of size would not always be available. Since size was considered important enough to document we decided to include an estimation of tumour size, as measured with a ruler, and the clinician's assessment of response, although subjective.

The time spent together in designing the data entry form has been a good investment. No data field is redundant and through discussion we obtained better insight into which data were feasible to collect and what was too ambitious. Additionally, it enhanced local ownership and active participation of individual centres and their leaders.

We want to keep data entry simple and accessible. The CRFs are in Microsoft Word. The local data entry person can complete the form with pen and paper or complete a computerised soft copy. Thereafter the forms are copied and collected centrally. Hard copies can be sent by ordinary mail and soft copies can be sent by email or placed in a dropbox. Transmitting soft copies by email or to a dropbox are preferred. Site clinicians supervise and check the data entry.

The person entering the data is more important than the data collection system. Training is important, but it is mostly the dedication and interest of the person entering the data that determines its quality and completeness. In our project the local clinical leaders arrange who will enter the data. The local lead supervises and checks all the forms before they are sent to the central co-ordinator. In Blantyre the data entry person joins the ward rounds, knows all the patients and coordinates the follow up.

Follow-up is challenging in low-income countries and especially in sub-Saharan Africa. Parents have other priorities than returning to the hospital with a healthy-looking child; funds are often lacking for follow up and when they are available, bad roads and lack of home addresses hamper outreach visits to the homes of patients. Mobile phones are not always available and there is limited facility for charging, as well as limited mobile phone network coverage in

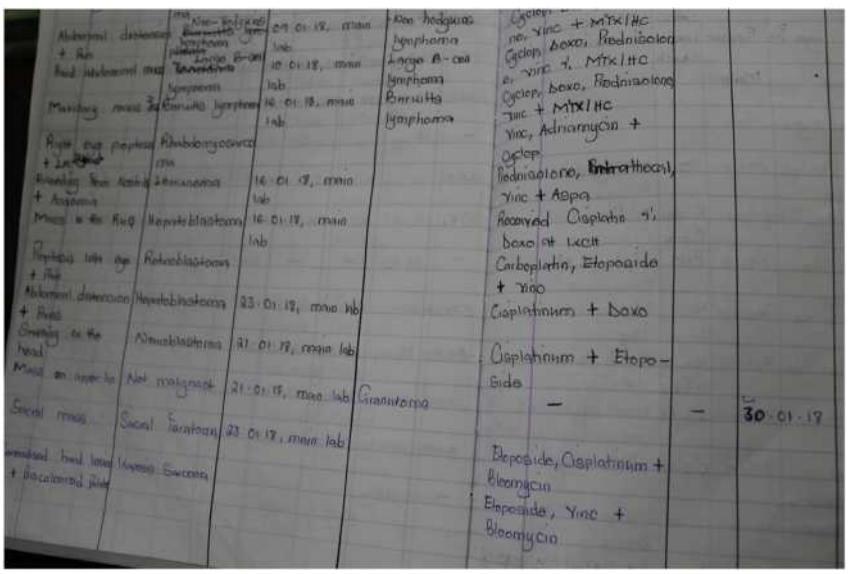

Fig. 3. A simple pen and paper system can work - admission book in Blantyre, Malawi.

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	SIOP AFRICA / PODC Collaborative Wilms Tumour Project	**PATIENT REGISTRATION FORM**

Patient Identifier (e.g. John Smith, male, born 15/12/1980 = JSM15121980) F S M/F D D M M Y Y Y Y	**SIOP Sequence No:**
	Centre: Queen Elizabeth Central Hospital, Blantyre, Malawi

1. At Admission / Diagnosis			
1.1 Patient Details			
Date of admission	xx	M / F	
First Name			
Family Name			
Date of Birth or Age (if known)			
Home address			
Town / Village		District	
Distance home – treatment centre (km)			
Contact (phone no.)		Phone owner	
Alternative phone no.			
Nearby church / school / landmark			
Map			
1.2 Patient Medical History			
Duration of symptoms			
Previous surgery / chemotherapy for this disease			

Fig. 4. Two pages of the case record form as an example.

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2. Surgery

Surgeon		Date of surgery	
Tumour looks like Wilms tumour	Yes	No	Not sure
Suspect different condition	Yes / No	If yes please specify	
Did you see any metastases	Yes / No	If yes please specify where	

	Did the following structures look:			Did you perform:		
	Normal	Suspicious	Obviously infiltrated	Complete resection	Incomplete resection	No resection
Renal vein						
Vena Cava						
Tumour capsule						
Lymph nodes						

Did you see a Tumour Capsule Rupture	Yes / No	If yes do you think this occurred	Preoperatively	During surgery	Do not know
Is this a	Major rupture	Minor rupture	Did you do a	Biopsy only	Total nephrectomy
If nephrectomy was is	Complete resection of an intrarenal tumour (surgical stage 1)	Complete resection of a tumour with extra renal extension (surgical stage 2)			Incomplete resection (surgical stage 3)

Any complications during surgery (please specify			
Was the surgery	Difficult / complicated	Simple, complete resection	
Did you have to (partially) resect organs (due to injury)	Yes / No	If yes which organ(s)	
Tumour weight	grams	Largest tumour diameter	cm

Fig. 4. (*continued*).

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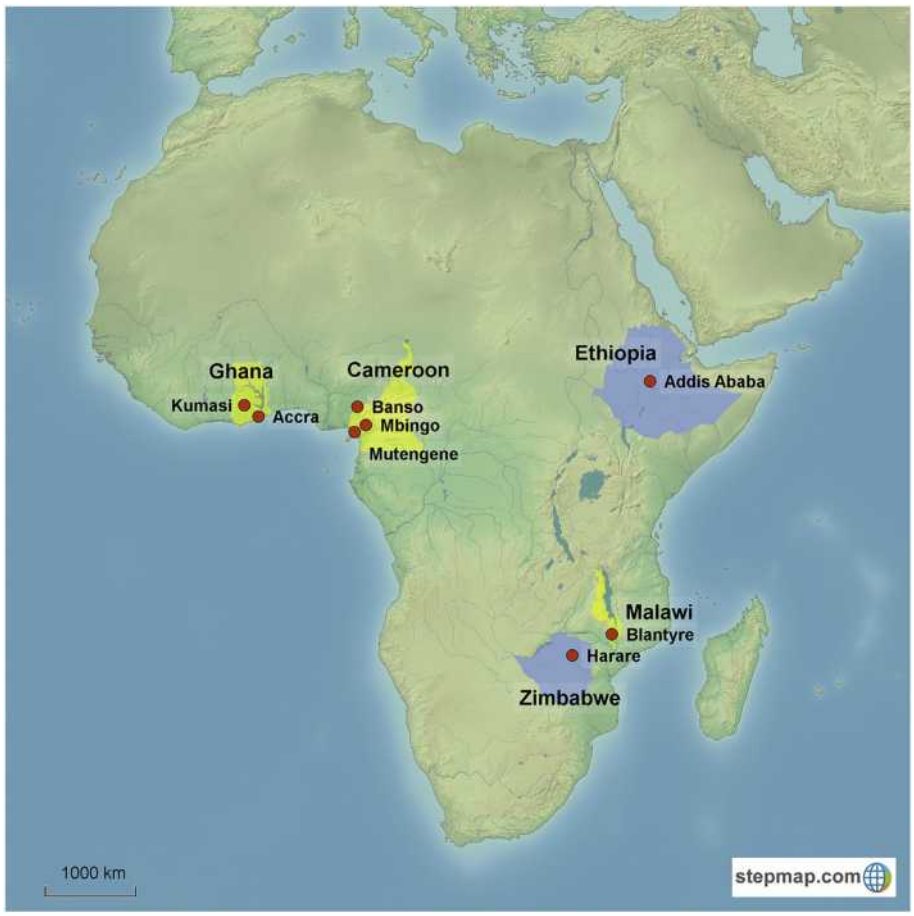

Fig. 5. Map showing the centres participating in Collaborative Wilms Tumour Africa Project.

rural areas. All of this means that survival data from low income countries with longer term follow-up are rare. However long-term follow-up is needed to record late relapses and establish the true survival rate.

At the work meeting in 2013 we discussed and agreed on the strategies to facilitate adequate long-term follow up in our project. Personal details of the patient and his or her parents are carefully documented at diagnosis. These include the home village, traditional authority and region. A home address is noted if available, but many homes do not have an address and it is more important to record landmarks near the home (e.g. a church, or a school) and relevant mobile phone numbers, including phone numbers of relatives or officials in the village. These details are essential when active follow up by phone or by visiting the patient's home is needed.

Someone in each centre is tasked to keep track of the patient after active treatment is completed. An excel sheet is kept with the names of all enrolled patients, the date they were last seen and their condition (well or relapse of disease). This excel sheet showing an overview of follow up is sent to the central coordinator about every six months.

The central database is in SPSS. Two medical students are helping to enter the data. They are familiar with SPSS and were trained to understand the CRFs and the questions underlying the different data points.

There are several challenges. Data entry, cleaning, integrating and analysis all take time, and everyone involved in the project has other duties, most often of patient care. It is a challenge to find time to do the work. For a dedicated data manager, it is not always easy to get good clinical supervision. In some centres it is a challenge to get forms completed by other participating disciplines such as pathology or surgery. However, as originally hoped for, overall this multi-disciplinary project has strengthened local inter-disciplinary activities.

The quality and completeness of the collected data has been excellent; less than 10% of data points are unfilled and only a few need clarifications by the central co-ordinating team. Careful pre-project planning has meant that very few modifications or explanations have been needed to assist data entry and completeness. Good documentation will help to assess the true impact of interventions in this regional network and will thus help to find sustainable solutions for local challenges to benefit children with cancer. Many of the lessons learned such as access to care, the need for early and definitive diagnoses and the difficulty and cost of follow up are all relevant to other chronic non-communicable diseases that are of increasing concern and prominence in LMICs. Perhaps the Wilms Collaborative Team Project can help to forge a path for others to follow.

Conflicts of interest

Authors declare no conflict of interest.

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Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.phoj.2018.09.001.

Reference

[1] Israels T, Kambugu J, Kouya F, El-Mallawany NK, Hesseling PB, Kaspers GJ, et al. Clinical trials to improve childhood cancer care and survival in sub-Saharan Africa. Nat Rev Clin Oncol 2013;10(10):599–604.