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RESEARCH ARTICLE

Availability of proper drug dose formulation in newborn care settings in Burdwan Medical College & Hospital

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ABSTRACT

Background: Absence of separate newborn drug dose formulation for most of the commonly used drugs results in wastage of resources, loss of efficacy, increased risk of contamination along with errors in dose administration. Our study looked forward to the availability of proper drug dose formulation in newborn care units of Burdwan Medical College & Hospital and in Najyamuller Aushadher Dokan along with nearby chemist shop. **Methods:** An observational study in newborn care units of Burdwan Medical College & Hospital was carried out for a period of 6 weeks. Commonly used drugs in newborn care units were analysed and compared with National Formulary of India, National List of Essential Medicines and IAP Paediatric Drug Formulary. **Results:** A total of 203 participants were enrolled. Most of the commonly used drugs were available either from the government supply or from the Najyamuller Aushadher Dokan in appropriate drug dose formulation except few. Most of them were listed in National Formulary of India, National List of Essential Medicines and IAP Paediatric Drug Formulary. **Conclusion:** Respective local and higher authorities should take up the responsibility to make avail all of the commonly used drugs in proper drug dose formulation with respect to newborn care settings.

Key words: Najyamuller, Aushadher Dokan

INTRODUCTION:

Burdwan Medical College is situated in Burdwan town of Burdwan district, West Bengal. It caters service to the people of this district and adjacent districts (Fig. 1), that is, Hooghly, Murshidabad, Purulia, partly Bankura and also people of Jharkhand and Bihar.[1]

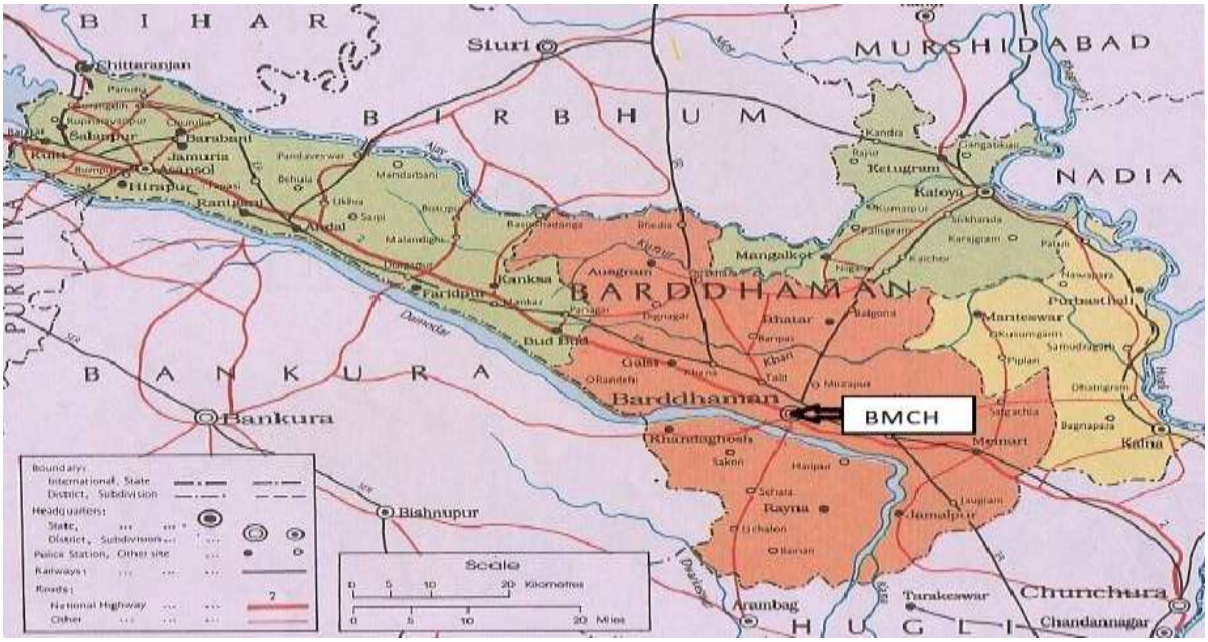

Figure 1: Catering region of newborn care units of Burdwan Medical College & Hospital (BMCH)

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Having Neonatal intensive care unit (NICU) and Special newborn care unit (SNCU), Burdwan Medical College & Hospital (BMCH) caters huge number of newborns. The rate of bed turnover in the month of December in BMCH (obtained in a cross-sectional study) was 77 in SNCU (24 bedded) and 125 in NICU (64 bedded).

Newborns, particularly the preterm, are the most vulnerable portion of our society for their small size, physiological immaturity and limited compensatory abilities.[2] The pharmacokinetics of a drug in neonate relate to its body composition including protein binding characteristics, organ weight and function (including renal and hepatic). As these characteristics do not develop linearly with age or weight, standardisation of a dosage (e.g., mg/kg) is not appropriate in neonate.[3]

Unfortunately, there is no separate newborn drug dose formulation for most of the commonly used drugs. Commonly, a fraction of the diluted adult or paediatric multidose vial is used for the purpose and the rest are stored in refrigerator for future use. This may result in wastage of resources, or use of a pre-diluted contaminated medicine causing adverse reactions, loss of efficacy and potency. This may even lead to nosocomial sepsis.[4,5] Again, unintended variability in dose administration, including dose and volume calculation, is inherent to any manipulation of drugs.[6,7]

Many pharmaceuticals are reluctant to manufacture newborn or even paediatric drug dose formulations for increased cost with lesser trading volume along with many unapproved drugs in the market.[4] These are depriving the neonates from proper dose formulations, although it is a basic right of a patient to obtain a right drug in right dosage in a right way.

With this background, we started our journey on and from 10/12/2014 to carry out a cross-sectional study to look for availability of proper drug dose formulation in newborn care units of Burdwan Medical College & Hospital (BMCH), including the Najyamuller Aushadher Dokan (Fair price retail outlet) within the hospital premises.

The primary objective of our study was to assess the availability of proper drug dose formulation in newborn care units of BMCH and in Najyamuller Aushadher Dokan[8] (NMAD) within the hospital premises along with nearby chemist shops within 5km. radius of hospital campus. Our secondary objective was to compare these with National Formulary of India[9] (NFI), National List of Essential Medicines of India[10] (NLEM) and IAP Pediatric Drug Formulary[11] (IDF).

METHODS:

After obtaining clearance from Institutional Ethics Committee (IEC), an observational cross-sectional study was carried out in newborn care units, which include Neonatal intensive care unit (NICU) and Special newborn care unit (SNCU), of Paediatric department along with labour room of Obstetrics & Gynaecology department of BMCH. Study subjects were the newborn in newborn care units of BMCH. Study was carried out for a period of 6 weeks from 10/12/2013 to 20/01/2014. Commonly used drugs in BMCH from government supply (Department of H& FW, West Bengal) and NMAD were assessed and compared with NFI, NLEM along with IDF.

RESULTS:

A. A total of 203 participants were enrolled from NICU and SNCU of Paediatric department along with labour room of Obstetrics & Gynaecology department of BMCH. Baseline characteristics of the participants are mentioned in Table 1.

Table 1: Baseline characteristics of the participant (n = 203)

Birth Weight in Kg.	Total (203)	Male (119)	Female (84)
< 1.5	28	14	14
1.5 to 2.5	56	41	15
> 2.5	119	64	55

B. Most of the commonly used drugs were available from the government supply or from the NMAD and were present in proper drug dose formulation with respect to newborn care settings. Commonly used drugs that were not present in proper drug dose formulation or which were not availed both from the government supply and from the NMAD are mentioned in Table 2.

Table 2: Commonly used drugs

Available as government supply but not in proper drug dose formulation	Not available as government supply but present in Najyamuller Aushadher Dokan (Fair price retail outlets), not in proper drug dose formulation	Neither available as government supply nor in the Najyamuller Aushadher Dokan, but availed from outside hospital campus within 5 km. radius
All the commonly used drugs in government supply was available in proper drug dosage formulation (with respect to newborn care settings)	Vancomycin (250mg as hydrochloride in vial)	Fluconazole (200mg/100ml)
	Amoxycillin with clavulinic acid (300mg)	Naloxone (20µg/ml, 2ml ampule)
	Calcium gluconate (100mg/ml, 10ml ampule)	VZIG (1.25ml/6.25ml)
	Dopamine (40mg/ml, 5ml vial)	
	Digoxin (250µg/ml, 2ml ampule)*	
	HBIG (100µg)*	

***Their supply is infrequent in Najyamuller Aushadher Dokan and many times have to be procured from outside the hospital campus within the 5km. radius
HBIG= Hepatitis-B immunoglobulin
VZIG= Varicella Zoster immunoglobulin

C. All the commonly used drugs except amoxicillin with clavulinic acid are used from the previous stock (stored for not >8 hrs. in the refrigerator, after which it is discarded). Amoxicillin with clavulinic acid are always used from the fresh solution.

D. All the commonly used medicines in the newborn care units are mentioned in the IDF. Most of the commonly used medicines in the newborn care units are mentioned in the NLEM, except Meropenem, Varicella Zoster immunoglobulin (VZIG) and Hepatitis B immunoglobulin (HBIG). Amoxycillin with clavulinic acid have been newly added in the NLEM. Similarly, most of the commonly used medicines in the newborn care units are mentioned in the NFI except VZIG and HBIG.

E. When the same drug is used for multiple patients at one time (ignoring indications of uses), one can save at least 15% of the amount of total drug used in unit time (as per our estimate) and which definitely add to the economical benefit.

DISCUSSION:

The people of Burdwan and nearby districts are quite lucky to get most of the drugs commonly used in newborn care units of BMCH in proper drug dose formulation. Albeit a handful of drugs as mentioned in Table 2 are not present in proper drug dose formulation with respect to newborn care settings although mentioned in the IDF, NLEM and NFI. At the end of our journey, we want to draw kind attention of respective local authorities and higher authorities to make these drugs available in proper drug dose formulation.

The need of formulary is not just to list medicines, but it goes a long way to rationalise drug therapy. U.K. and Italy are fortunate enough to have separate drug formulary for paediatric age group.[12] India should come forward too to build up its own National drug formulary for paediatric age group (though IAP Drug Formulary exist). Standard Treatment Guidelines separately for newborn is to be kept in mind, though it lies in its infancy in West Bengal.

Our study was a single centre study restricting the generalisation of results. This type of study must be carried out in different centres on a nationwide basis to obtain a real scenario. This will help the higher authorities to bring regulations and take necessary actions.

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