



Pressure and Uncertainty of Conducting Ethics Reviews During a Pandemic: How can Research Ethics Committees Cope? Experiences from Zambia

EthiXPERT Webinar : Conducting Ethics Review During a Pandemic: How can Ethics Review Committees in LMIC leverage on available resources and skills?

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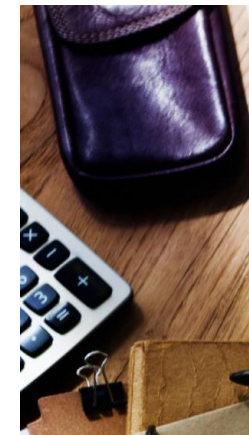
9th December 2021

Background

- The COVID-19 pandemic has disrupted many socio-economic activities including research (research ethics)
- Urgency to conduct research and development of solutions (biomedical/medical and public health) to address the pandemic
- Urgency for research regulatory players (Research ethics Committee and Government competent authorities) to approve protocol expeditiously
- **Challenge:** Rapidly implementing procedural modifications without compromising ethical standards

Experiences of UNZABREC

- First two cases of COVID-19 were reported on 18th March 2020
- Immediate closure of Universities, Schools, travel, **suspension of clinical research, meetings (face-to-face)** etc
- UNZABREC had just started using Rhinno (online submission system)
- Surge of mobile banking platforms



University of Zambia Biomedical Research Ethics Committee

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UNZABREC Procedural modifications

- 100% Online submission, review and feedback
- Online meetings (Zoom video conference)
- Introduced Fast-track review system (2 weeks turnaround)
 - Minimal risk studies only
 - Not clinical trials
- All COVID-19 protocols were Fast-tracked
 - Clinical trials?
- Use of independent experts (no voting rights)



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Challenges

- Waiver requests (Even for moderate to high risk studies)
- Waivers for consent
- Waiver for written informed consent
- Urgent protocols
- Requests to publish collected data (retrospective ethical approval)
- Thin line between clinical practice and research

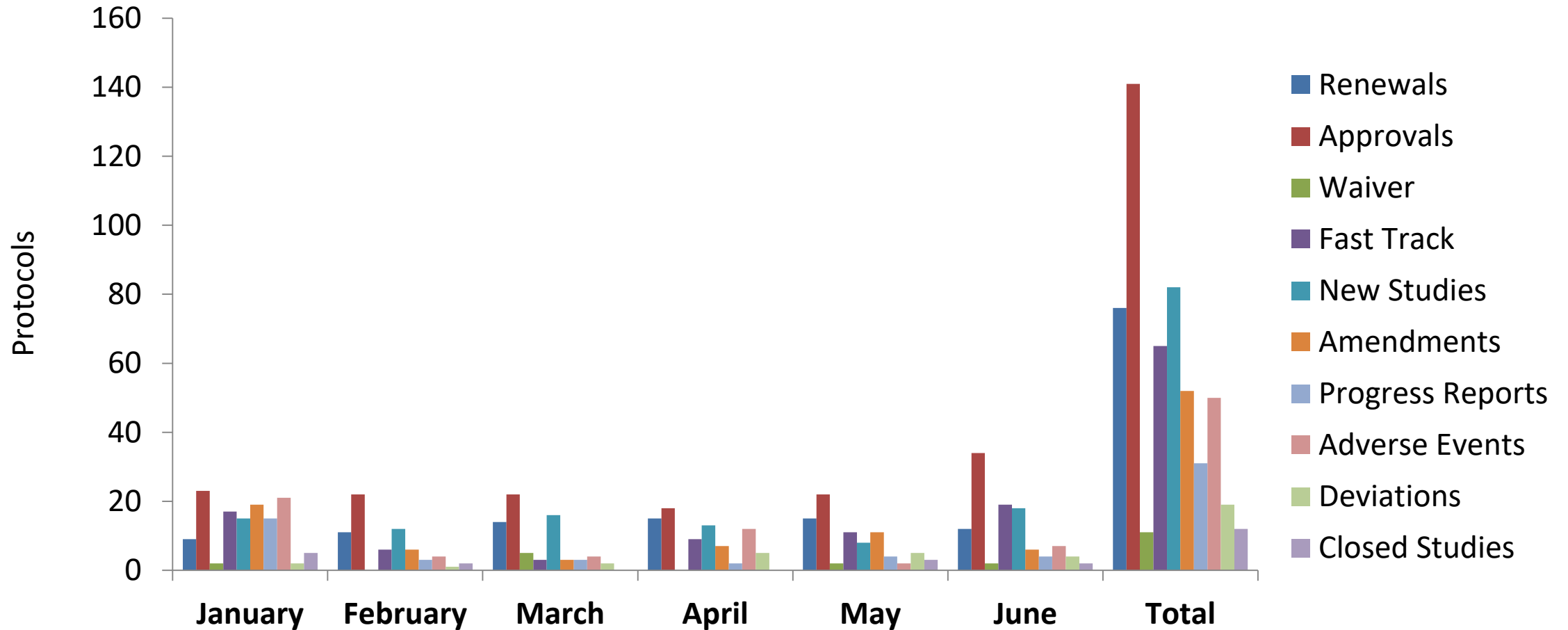
Best Practices adopted during review

- Weighing of risks and benefits (Beneficence)
- Review of COVID-19 measures to protect both participants and researchers (Beneficence)
- Extraordinary review meetings (via online platforms); Reduced quorum?
- Challenges of written informed consent?
 - Digital signatures?
 - Phone consent?
- Online training and webinars (NIH, G11 grant supported)

Protocol submissions for 2020

SUBMISSION TYPE	JAN	FEB	MAR	APRIL	MAY	JUNE	TOTAL
Renewals	09	11	14	15	15	12	76
Approvals	23	22	22	18	22	34	147
Waiver	02	00	05	00	02	02	11
Fast Tracks	17	06	03	09	11	19	65
New Studies	15	12	16	13	08	18	82
Amendments	19	06	03	07	11	06	52
Progress reports	15	03	03	02	04	04	31
Adverse Events	21	04	04	12	02	07	50
Deviations	02	01	02	05	05	04	19
Closed Studies	05	02	00	00	03	02	12

Protocol submissions for 2020

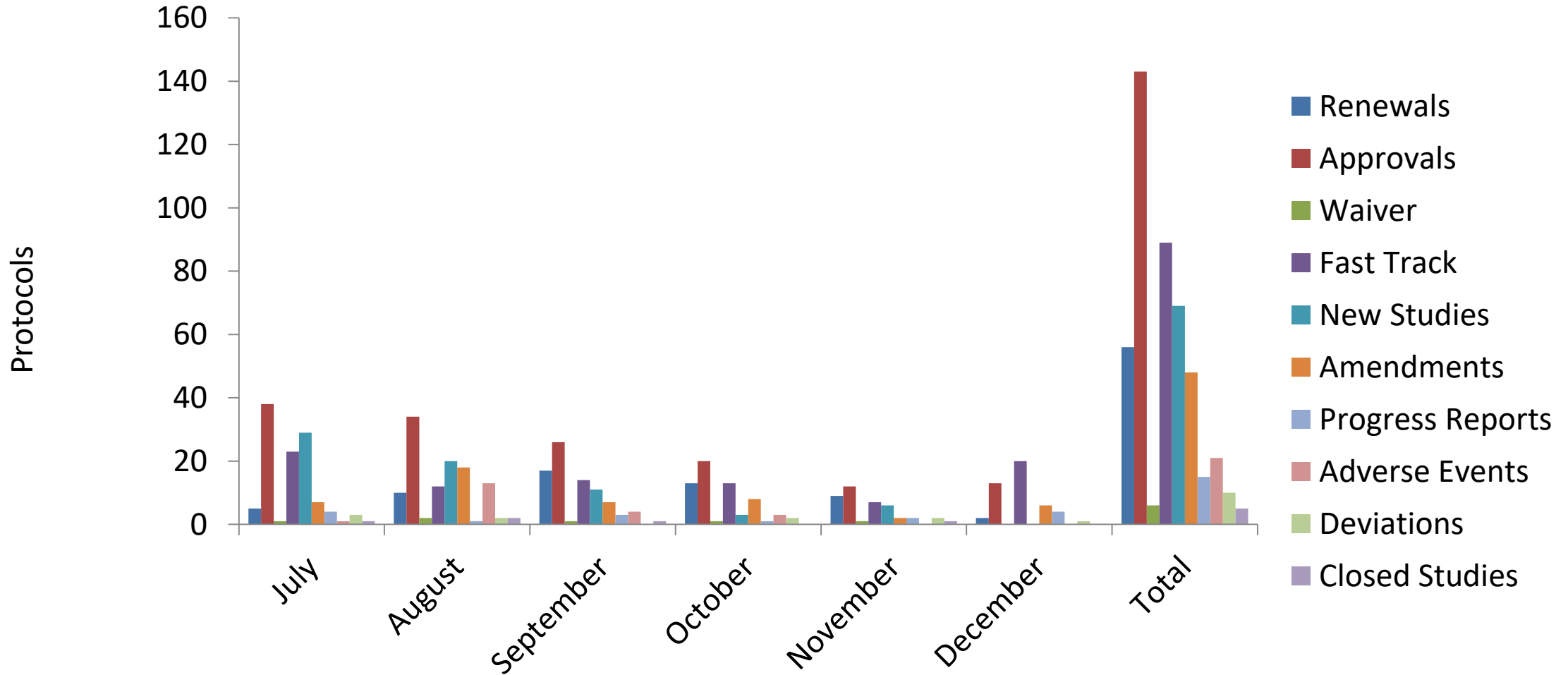


Protocol submissions for 2020

SHOWING SUBMISSIONS FROM JULY TO DECEMBER

SUBMISSION TYPE	JUL	AUG	SEP	OCT	NOV	DEC	TOTAL
Renewals	05	10	17	13	09	02	56
Approvals	38	34	26	20	12	13	143
Waiver	01	02	01	01	01	00	06
Fast Tracks	23	12	14	13	07	20	89
New Studies	29	20	11	03	06	00	69
Amendments	07	18	07	08	02	06	48
Progress reports	04	01	03	01	02	04	15
Adverse Events	01	13	04	03	00	00	21
Deviations	03	02	00	02	02	01	10
Closed Studies	01	02	01	00	01	00	05

Protocol submissions for 2020



Questions and Comments?

Thank you!
