

**USING CLINICAL RESEARCH AS A TOOL FOR
IMPROVING CLINICAL COMPETENCES AMONG
CLINICAL STUDENTS**

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Clinical Research

- “The systematic investigation into and study of materials and sources in order to establish facts and reach new conclusions.”
- *Good Clinical Practice (GCP)* is the basis for quality and human subject safety in all clinical research and provides guidance that must be strictly adhered to before, during, and after a research study is undertaken
- Research is critical to improving patient outcomes and the quality of healthcare.
 - It helps us to understand what works, what doesn't work, and why.
 - Research is essential for developing new treatments and therapies.
 - Research: lifesaving vaccines and medications that we take for granted today.

Clinical Research

- Research, clinical care, and education are very important for any country including our country Kenya.
- Hospitals with heavy research components have better outcome which is also tied to availability of funds and funding opportunities.
- Mentoring is important:
 - Productivity
 - Career development
 - Leadership skills
 - Work culture
 - Collaboration
 - Essential in supporting ongoing research activity

Is research important for undergraduates?

- Improve your communication skills
- Find opportunities to present and publish your ideas
- Test your determination and perseverance
- Develop
 - Creativity/innovation
 - Problem-solving
 - Intellectual independence

How do you engage medical students in research?

- Educate students on the benefits of research
- Encourage students to
 - Take initiative to create opportunities for themselves
 - Undertake extracurricular research
 - Network with other researchers
 - Engage with student-selected components of their courses
 - Attend scientific conferences
 - Do research during elective placements
- Emphasize research as a learning process

Picking your research project: The 3 Ps

- Person
 - Are you ready
- Project
 - Which project...
 - Basic or Laboratory-based research
 - Clinical Trials
 - Epidemiological Research
- Place
 - Is the place known for that type of research
- Plus, professional and Personal Development
 - Learning a new research method
 - Writing a grant proposal or research protocol, or submitting to research ethics?
 - Training courses could you attend to support your personal and professional development?

Making the most of research opportunities

- Presentation
 - National or international meetings
 - Build network
 - Improve your presentation skills
- Prizes and awards
 - Student awards
 - Conference prizes
- Publications
 - Preferably peer reviewed

Challenges and barriers to establishing and sustaining a Clinical Research

- Financial and human capacity
 - Funding
 - Skilled personnel
- Ethical and regulatory system obstacles
 - Delayed approval
 - Tortuous approval processes
- Lack of research environment
 - Infrastructure
 - Conducive environment
- Operational barriers
 - Unsupportive administration
- Competing demands
 - Lack of time
 - Other competing demands

Conducive Environment for Clinical Research

- Sponsor
 - Effective communication
- Regulators
 - Rigorous but less tortuous processes
- CROs
 - Proactive
- Vendors
- Investigators

High Impact research from students

**BACTERIAL PATHOGENS AND
ANTIBIOTIC SUSCEPTIBILITY
PATTERNS AMONG NEONATES WITH
SEPSIS AT KENYATTA NATIONAL
HOSPITAL, NEWBORN UNIT.**

Table 3. Organisms isolated

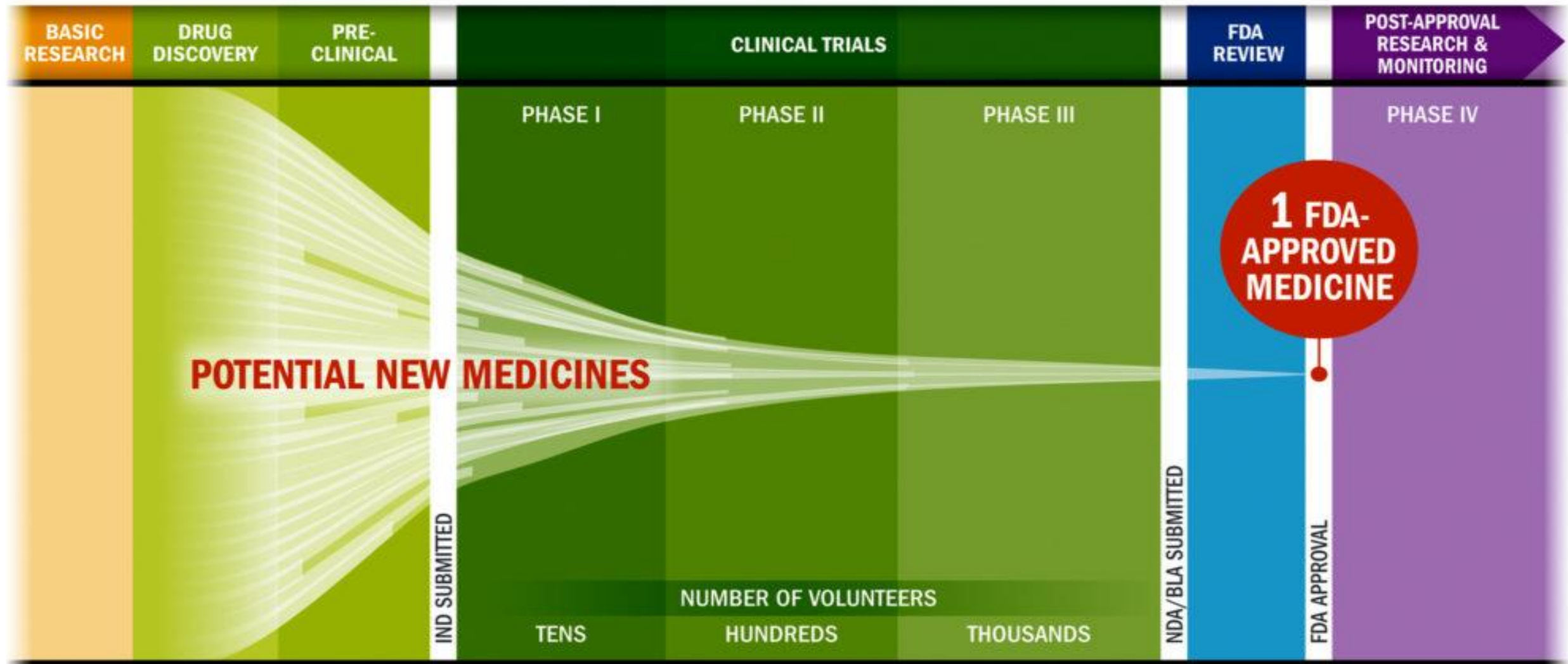
	Isolates	n=158(%)
1.	<i>Klebsiella pneumoniae</i>	43 (28.9)
2.	<i>Staph epidermidis</i>	27(18.1)
3.	<i>Pantoea agglomerans</i>	18(12.1)
4.	<i>Serratia marcescens</i>	15(10.1)
5.	<i>Enterococcus faecalis</i>	11(7.4)
6.	<i>Staph haemolyticus</i>	8(5.4)
7.	<i>Micrococcus species</i>	4(2.7)
8.	<i>Coagulase negative staph</i>	4(2.7)
9.	<i>E. coli</i>	3(2.0)
10.	Other bacteria	15(9.3)

Table 4. Susceptibilities of commonly used antibiotics

	Antibiotic	Totals isolates	Sensitive (%)	Intermediate (%)	Resistant (%)
1	Amikacin	83	73(88)	9(11)	1(1)
2	Amoxicillin/Clavulanate	82	4(5)	18(22)	60(73)
3	Benzylopenicillin	46	3(7)	0(0)	43(93)
4	Ceftazidime	81	2(2)	1(1)	78(96)
5	Ceftriaxone	85	2(2)	1(1)	82(96)
6	Cefuroxime	80	1(1)	0(0)	79(99)
7	Ciprofloxacin	86	75(87)	0(0)	11(13)
8	Clindamycin	36	13(36)	0(0)	23(64)
9	Erythromycin	52	10(19)	1(2)	41(79)
10	Gentamycin	124	36(29)	1(1)	87(70)
11	Meropenem	85	74(87)	3(4)	8(9)
12	Piperacillin/Tazobactam	70	21(30)	7(10)	42(60)
13	Trimethoprim/Sulfamethoxazole	91	35(38)	0(0)	56(62)
14	Vancomycin	48	43(90)	1(2)	4(8)

Results/Conclusion

- A total of 357 blood culture samples were analyzed from the NBU, of which
 - 158 were positive (44.2%).
 - More than half (54%) of the cases had late onset sepsis.
 - Gram negative isolates were predominant at 58% and associated with poor outcome with mortality rate of 56.3% (O.R 4, 95% CI: 1.4-11.2, p=0.007).
 - Klebsiella pneumoniae was the leading isolate at 28.9%.
 - High resistance rates above 95% were noted to cephalosporins.
 - Vancomycin and amikacin had high sensitivities of 90% and 88% respectively that of ciprofloxacin and meropenem was 87%.
- Conclusion Gram-negative sepsis predominated by K. pneumoniae accounts for majority of neonatal sepsis cases and is associated with high mortality and morbidity.
- Many isolates demonstrated high sensitivity to vancomycin, amikacin, ciprofloxacin and meropenem.
- High resistance rates to commonly used antibiotics particularly, cephalosporins and benzylpenicillin were noted



Key: IND: Investigational New Drug Application, NDA: New Drug Application, BLA: Biologics License Application

* The average R&D cost required to bring a new, FDA-approved medicine to patients is estimated to be \$2.6 billion over the past decade (in 2013 dollars), including the cost of the many potential medicines that do not make it through to FDA approval.

Source: PhRMA adaptation based on Tufts Center for the Study of Drug Development (CSDD) Briefing: "Cost of Developing a New Drug," Nov. 2014. Tufts CSDD & School of Medicine., and US FDA Infographic, "Drug Approval Process," <http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/UCM284393.pdf> (accessed Jan. 20, 2015).

Other high impact research carried out within this region

- Kwambai TK, Dhabangi A, Idro R, et al. Malaria Chemoprevention in the Postdischarge Management of Severe Anemia. *N Engl J Med*. 2020 Dec 3;383(23):2242-2254. doi: 10.1056/NEJMoa2002820
- Li, Q., Remich, S., Miller, S.R. *et al.* Pharmacokinetic evaluation of intravenous artesunate in adults with uncomplicated *falciparum* malaria in Kenya: a phase II study. *Malar J* **13**, 281 (2014). <https://doi.org/10.1186/1475-2875-13-281>
- The RTS,S Clinical Trials Partnership. **First Results of Phase 3 Trial of RTS,S/AS01 Malaria Vaccine in African Children.** *N Engl J Med* 2011;365:1863-1875.
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Conclusion

- Clinical research improves our lives
 - leads to significant discoveries
 - Improves health care
 - Ensures that patients receive the best care possible.
 - Makes the development of new medicines and treatments possible
- Gauge
 - Publication in high impact journals
 - Number of protocols
 - Research funds/dollars
 - Protocol deviations/violations
 - Audit outcomes
 - Enrollment goals and retention

Thank You

References

- 'CEDAM'
- Dr Achola dissertation, UON
- <https://undergradresearch.wustl.edu/benefits-undergraduate-research#:~:text=Undergraduate%20research%20can%20help%20you,test%20your%20determination%20and%20perseverance>
- Mabvuure NT. Twelve tips for introducing students to research and publishing: a medical student's perspective. Med Teach. 2012;34(9):705-9. doi: 10.3109/0142159X.2012.684915. PMID: 22905656