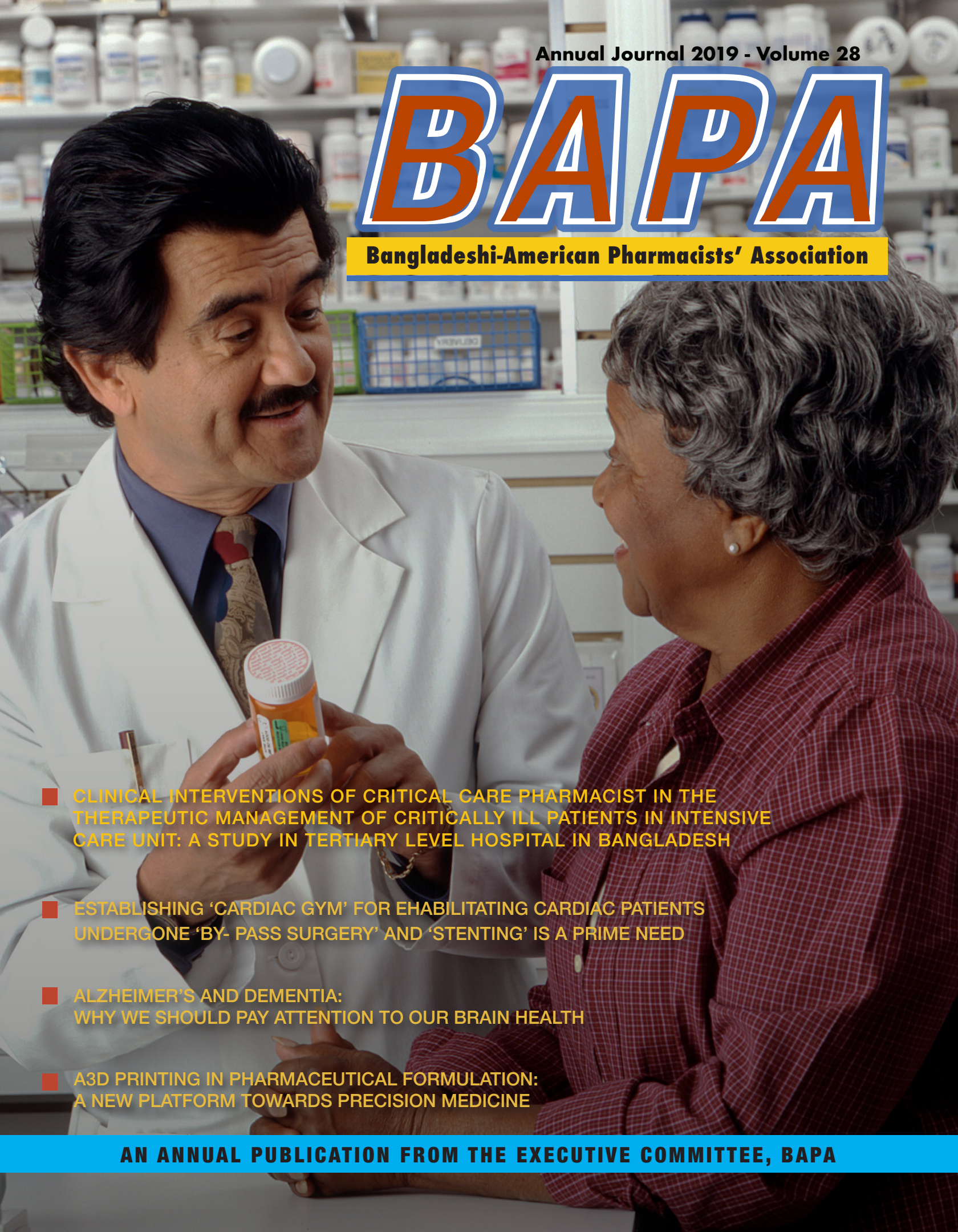
Annual Journal 2019 - Volume 28

BAPA

Bangladeshi-American Pharmacists' Association



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Departed Souls

We deeply regret and mourn the departure of our fellow friends.
We miss them a lot and remember them in our prayers.
In this day of the Convention we will miss their presence.

Abdullah Al Sad

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Disclaimer: If we missed anybody's name it is an unintentional mistake.

EDITORIAL

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28th Annual Convention Programs

AUGUST 16TH - 18TH, 2019

HARTFORD MARRIOTT DOWNTOWN

200 Columbus Blvd, Hartford, CT 06103

BAPA CONVENTION SCHEDULE AT-A-GLANCE

Day 1	Friday, August 16, 2019
12:00 PM - 8:00 PM MARRIOTT A, B FOYER	Registration
7:00 PM - 8:00 PM CAPITAL 1	**CONTINUING EDUCATION:** **Drug Regulatory Process Overview- An US Perspective** **Presenter:** Naushad Islam, Senior Director & Global Regulatory Leader, Janssen Oncology, J&J
8:00 PM - 10:00 PM MARRIOTT A, B, C	Dinner
10:00 PM - 12:00 AM MARRIOTT A, B, C	Cultural Show
11:00 PM - 11:30 PM MARRIOTT A, B, C FOYER	Refreshments

Day 2	Saturday, August 17, 2019
8:00 AM - 10:00 AM MARRIOTT A, B, C	Breakfast
9:00 AM - 1:00 PM CAPITAL 1	**CONTINUING EDUCATION:** **2019 Pharmacy Compliance Update** **Presenter:** James Schiffer RPh., ESQ, Allegaert Berger & Vogel LLP and Carlos Aquino, Founder of PharmaDiversion LLC
11:00 AM - 11:30 AM CAPITAL FOYER	Refreshments
1:00 PM - 2:00 PM MARRIOTT A, B, C	Lunch

2:30 PM - 4:00 PM **CONTINUING EDUCATION:**
Understanding the 2018 Cholesterol Guidelines
Presenter: Dr. Shushama Alam, Pharm.D., Senior Regional Medical Liason at Amgen

4:00 PM - 5:30 PM **CONTINUING EDUCATION:**
Tobacco Cessation for Pharmacists
Presenter: Dr. Jennifer Bhuiyan, PharmD, Assistant Professor, St. Johns University

3:00 PM - 3:30 PM Refreshments
CAPITAL FOYER

7:30 PM - 12:00 AM **Dinner and Cultural Program**
MARRIOTT A, B, C
Keynote Speaker: Qazi A Halim, MS, R.Ph., Former Director of Pharmacy, Brookdale Hospital Medical center, Brooklyn, NY.
Director, Contracted Pharmacy Services, Medisys Management LLC, NY (Part-time).
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President-Royal Counties of NY Society of Hospital Pharmacists: 2000-01
President-New York State Council of Health System Pharmacists 2013-14.

11:00 PM - 11:30 PM Refreshments
MARRIOTT A, B, C FOYER

Day 3 | Sunday, August 18, 2019

8:00 AM - 10:00 AM **Breakfast**
MARRIOTT A, B, C

10:00 AM - 12:00 PM **CONTINUING EDUCATION:**
CAPITAL 1 **CAR-T Therapy**
Presenter: Dr. Rafi Reyasat, PharmD, Pfizer

12:00 PM **Hotel Check Out**

For further update or changes, please visit our website at http://www.bapana.org

YOGA: **Conference Room 7 (Saturday 11:00 am)**

PRAYER ROOMS : **Conference Room 4 AND 5**

SAREE VENDORS SHOWCASE: **Marriott D, E**

PHARMACY VENDORS: **Capitol Foyer**

Message from the PRESIDENT

Helal Mohiuddin

Welcome to the 28th Annual BAPA Convention.

Heartfelt Thanks to our members, guests and sponsors for joining us this year and committing to make the event a success.

At BAPA, we combine the personal with the professional, pairing rigorous conversations on hot topics in the Health Care Sector with multiple opportunities to network and have fun with those we care about in our lives.

Pharmacy is an honorable profession in the world, including USA. We recognize the importance of pharmacists in improving the health and quality of life for all. Our program is designed to help you reach new levels of excellence in your careers and serve patients to the best of your abilities. We use this special weekend to disseminate new knowledge, exchange ideas, and plan ahead for future generations excited by this work.

There are myriad issues that came up this year for many of us in the industry, including new business models in healthcare delivery that gave competitive advantages to large companies, policy reforms on drug pricing, international trade relations and more. I welcome everyone to share resources you've read on these challenges and discuss how we can create solutions in the coming year.

In addition to national issues, we'll continue our conversation on further improving and developing the pharmaceutical sector in Bangladesh. If we can help our home country ensure global standards, it will open opportunities for investment, which will ultimately help improve the quality of drugs that reach the public in Bangladesh. I think we can all agree that is an important goal for us all.

The print edition of BAPA's Annual Journal for 2019 (Volume 28) is available to help guide you through some related topics and I thank the editorial board and executive committee for their efforts to produce such an excellent journal.

Finally, I would like to thank you all once again for your continuous support and helping to make the 28th Annual BAPA Convention a success.

Warmly,

Helal Mohiuddin

President

Message from the VICE PRESIDENT

Naushad Islam

Welcome to our 2019 annual convention.

As we celebrate another banner year of the Bangladeshi-American community moving forward in the profession of pharmacy, I want to remind everyone about the need to stay united to face the challenge of changing health care landscape.

With rising health care cost and competitive environment, it is becoming increasingly difficult for our fellow Pharmacist to provide quality care to our customers despite utmost sincerity. It is also important to encourage our new generation of pharmacists to explore other diverse professional areas of Pharmacy profession beyond retail pharmacy.

I am pleased to welcome all our vendors that join us every year and hope our relationships will continue to benefit each other. This year, I would also like to thank our biggest sponsors, Kinray and Micro Merchant, for making this convention successful.

Personally, I want to thank the BAPA members for their strong continued support to allow me to serve as BAPA Vice-President for 2019. It is my sincerest hope to maintain the level of excellence of my predecessors while continue creating new path as we move forwards in the future of challenging US Health Care.

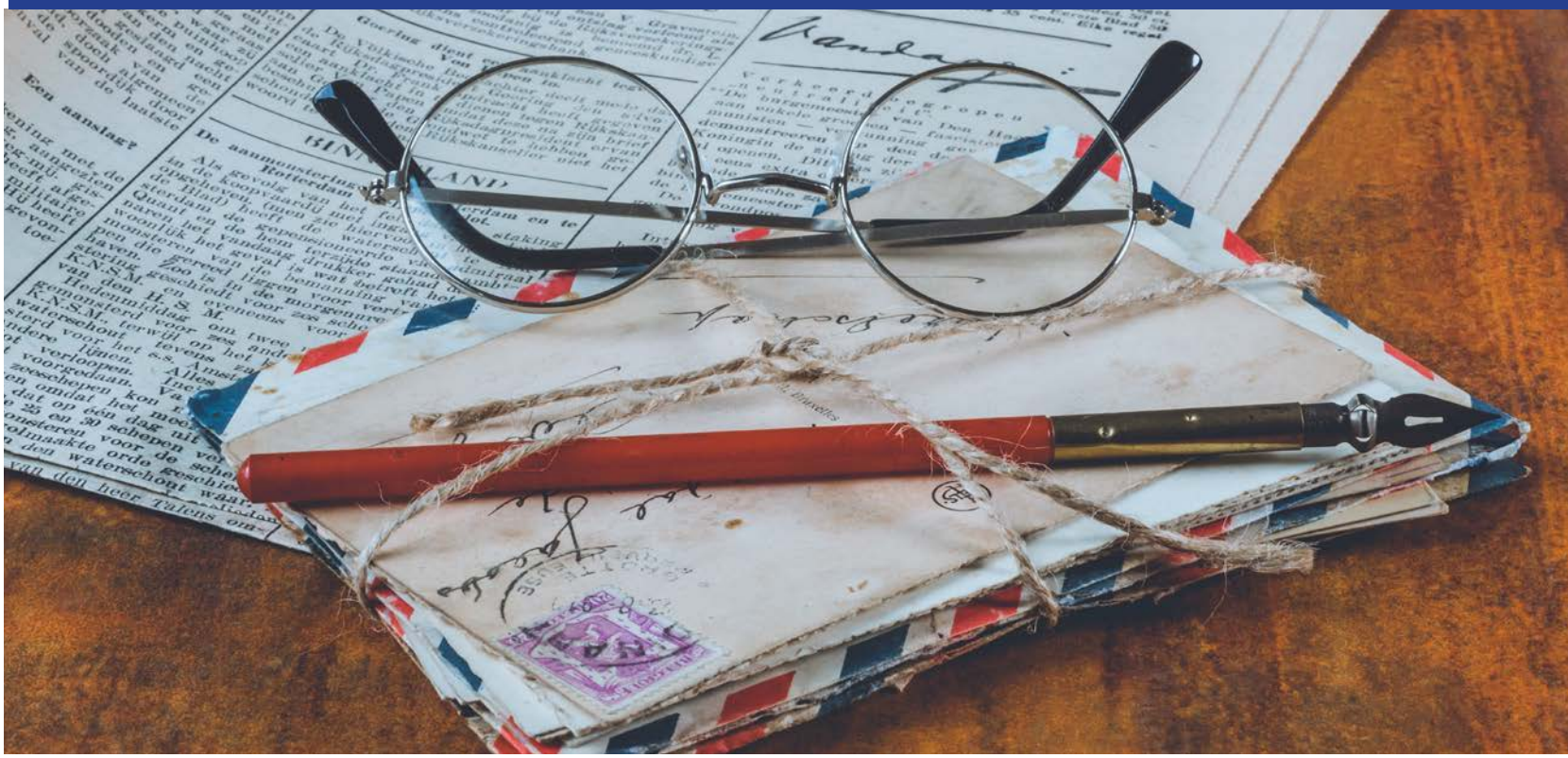
We are also seeing more and more Bangladeshi Pharmaceutical Companies making inroads in the US market through collaboration. I sincerely hope their increased presence in US market will help strengthen the relationship with BAPA and our fellow pharmacy colleagues in the coming days. This relationship hopefully will provide mutual benefit to our members as these companies will continue to seek US trained Pharmacy professionals.

Regarding BAPA, the organization can only continue with your support and increased participation. Through this message, I urge you to continue your blessings for this organization and encourage future Pharmacists from this community to join BAPA as well. Please do not hesitate to communicate any questions, comments, or concerns either to me or any BAPA executive members. We hope to see you in this year's convention.

Naushad Islam

Vice President

articles



Clinical Interventions of critical care pharmacist in the therapeutic management of critically ill patients in intensive care unit: a study in tertiary level hospital in Bangladesh

Md Jahidul Hasan[1*], Raihan Rabbani[2], Sitesh C Bachar[3]

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Abstract

Critically ill patients at intensive care unit (ICU) are treated with multiple and conservative drug management is necessary for ensuring drugs' safety and accuracy. The objective of this study was to analyze the qualitative intervention of critical care pharmacists (CCP) of critically ill patients in ICU with effective medication management. This was a 6 months long observational study. All the provided suggestions of CCP were categorized into- A (drug-drug interaction), B (addition of new drug therapies), C (rational dosing of antibiotics), D (acceleration or deceleration of the doses) and E (adverse drug reaction). Out of total CCP's 650 suggestions, 566 (87.08%) suggestions were accepted by clinicians and modified the therapies, accordingly. CCP being a part of ICU's multi professional team contribute the professional roles in generating safe, appropriate and quality prescriptions, which finally turns into quality pharmacotherapy for critically ill patients at ICU.

Keywords:
Critical Care Pharmacist; Intensive Care Unit; Critically ill patients; Multi professional team

INTRODUCTION

The perception of taking special care for critically ill patients firstly introduced in 1954, by Florence Nightingale during the Crimean War.[1] In 1954, first multidisciplinary intensive care unit (ICU) was established in USA.[2] Critical care pharmacy service, as a core clinical pharmacy profession, began around 1970s.[3] The clinical pharmacists of ICU, also known as, Critical care pharmacists (CCP), is one of the most useful and supporting persons in the ICU team, and a CCP is a trained specialist of ICU's conservative pharmaco-therapies, pathophysiology of critical diseases and pharmacokinetics/pharmacodynamics of drugs. They have amalgamated clinical knowledge and practical experience on effective poly-medication therapy for critically ill patients and being a core ICU team member, CCP plays his potential roles in the comprehensive treatment management for ensuring medication safety and optimum effectiveness of medications.[4]

Patients at ICU are at high risk of potential medication-induced adverse drug reactions, drug-drug or drug-disease interactions, dose related drug toxicity and some cases of inadequate drug therapy.[5] The disease and treatment complexity of critically ill patients at ICU is due to patients' poly-medication therapies, which make the pharmacological evaluations of the medications significantly tough.[6] A multiple studies showed that presence of critical care pharmacists reduce prescription medications errors, improve patient-treatment outcomes, ensure cost effectiveness of medications, minimize wastage of drugs and reduce overall mortality rate in most of the disease conditions.[7,8] In 2006, in United states, a survey was done over 1034 ICUs of 382 hospitals, only 62.2% of ICUs reported that they have clinical pharmacy services, and pharmacists participate in ICUs' grand round is 4.4 +/- 1.5 days/week and at least 75% of patient ICU days, they involve in fundamental clinical pharmacy activities.[9]

As a member of the ICU's multi professional team, critical care pharmacist inputs his additional values in the targeted patient care by suggesting doctors mostly in prescribing the medications appropriately, monitoring drug administration and efficacy of administered medications and giving drug related up to date information

to healthcare professionals.[9,10] Under the provision of clinical pharmacy, the existence of a dedicated pharmacist at ICU setup systematically ensures the development of some essential tools for better patient care service like, conservative treatment guidelines for critically ill patients management, different drug-treatment policies, pharmaceuticals care monitoring protocols, incorporation of new or latest drug therapies in the ordinary treatment paradigm and so on.[11]

In Asia and in most of the developing countries, the role of clinical pharmacists and the possible advantages of having pharmacists in clinical activities are not well understood by the healthcare professionals as those are well established from many years ago in most of the developed countries like, USA and UK.[12] In Bangladesh, the journey of hospital pharmacy started around 2005 and till today, this service is limited in few tertiary level private hospitals of some mega cities. Following that initiation of hospital pharmacy practices in Bangladesh, Square hospitals ltd., a tertiary level private hospital in Dhaka, as a local pioneer, initiated the Clinical pharmacy activities since its inception in 2006. Due to various reasons, this service was stopped after few years and started again through establishing 'Critical care pharmacy service' in 2015, especially at adult ICU department with one dedicated clinical pharmacist, named as 'Critical care pharmacist' and that clinical pharmacy support had been extended soon to other critical care areas like, CCU, Neuro-ICU, HDU, Neonatal-ICU, Pediatric-ICU, successfully. The continuous professional contributions of critical care pharmacist were appreciated and accepted by the concerned doctors and other medical staffs and as a result, day by day that service became the cornerstone of the critical patient care management at critical care areas of that hospital. The target of this study was to analyze the contributions of a critical care pharmacist in the therapeutic management of critically ill patients at ICU of a tertiary level hospital.[13]

Materials and Methods

The 8 months' data (March, 2018 to October, 2018) for this study were collected from the master service-record data of general adult ICU department of Square

hospitals ltd., Dhaka, a tertiary level hospital in Bangladesh. During that period, CCP clinically served total 828 critically ill patients in the ICU and 792 patients' data were considered for the study purpose. The rest of the admitted patients' data were not considered for the study because CCP did not find any suggestion from their prescriptions. The ratio between patients and CCP in that ICU was 8:1.

Data collection process for this study was based on the records of regular critical care pharmacists' patient-wise suggestions to doctors of the ICU and the responses of the doctors in respect to those suggestions on real-time basis.

The flow of CCP's suggestion

The CCP analyzed all prescribed medications and laboratory reports of every ICU patient before participating in ICU doctors' grand round once in the morning everyday and during round time, CCP shared the associated findings and suggestions to the consultant doctor (head of round team). After reviewing prescriptions, CCP provided drug-related suggestions, also concerning the current associated-diseases or disease progression in a manual individual patient-wise form, named as 'Pharmacist's Suggestion Form' and doctors followed-up those suggestion-notes written by the CCP. The final decision always was taken by the consultant doctors and if accepted, changes were made accordingly. Beyond the doctors' grand round, CCP routinely checked up medications of the prescriptions of patients as per the requirement and newly generated suggestions were shared to the doctors, spontaneously. CCP's provided suggestions and associated modifications of the prescriptions were categorized as follows-

A. Drug-drug interaction associated modification or deletion of drug therapies
B. Addition of new drug therapies
C. Rational dosing of antibiotics
D. Adjustment of the doses of prescribed medications
E. Prescribed drug induced adverse drug reaction

The CCP recorded patient-wise all the suggestions he forwarded to doctors and the number of suggestions accepted accordingly by the doctors in the hospital's own online record system. All those data of this study were analyzed by using IBM SPSS software (version 22). The ethical approval for this study was taken on February, 2018 from the hospital ethical committee.

RESULTS

CCP reviewed all critically ill patients' prescribed medications from the day of admission to the day of discharge from ICU. Among the total 8,28 (N) critically ill patients, CCP worked on 7,92 patients (95.65%; N= 828) and made 650 (82.07%) suggestions for doctors' considerations (table 1). CCP found 36 (4.35%) patients' prescriptions where no suggestion required (table 1).

Table 1: Review of prescriptions and CCP's suggestions

Total patients admitted (N)	Number of patients' prescriptions reviewed and %	Number of suggestions given and %	Number of prescriptions required no suggestion and % (N= 828)
828	792 (95.65)	650 (82.07)	36 (4.35)

CCP analyzed all prescribed medications of prescriptions in the drug safety's point of view and after reviewing drug therapies, they made suggestions for doctors considering all five categories (A, B, C, D & E) in order to make the drug therapies appropriate, safe and effective. In this study, among 650 CCP's suggestions, under category-A (Drug-drug interaction associated modification or deletion of drug therapies), category-B (Addition of new drug therapies), category-C (Rational dosing of antibiotics), category-D (Acceleration or deceleration of the doses of prescribed medications) and category-E (Prescribed drug induced adverse drug reaction), 84 (12.92%, n= 650), 102 (15.69%, n= 650), 358 (55.08%, n= 650), 57 (8.77%, n= 650) and 49 (7.54%, n= 650) (table 2) suggestions were generated by CCP, respectively, and placed to doctors for further therapeutic considerations and modifications of prescriptions, accordingly. Among all the suggestions given by the CCP during that time-period, the highest number of suggestions came under the category C (Rational dosing of antibiotics) (358 suggestions, 55.08%, n= 650) (table 2) and the

lowest number of suggestions came under the category E (Prescribed drug induced adverse drug reaction) (49 suggestions, 7.54%, n= 650) (table 2).

Table 2: Categorization of suggestions

Suggestion Categories	Number of suggestions given	Total suggestions given (%)	Number of suggestions accepted by doctors	Total suggestions accepted by doctors (%)
A	84	12.92	73	86.90
B	102	15.69	88	86.27
C	358	55.08	326	91.06
D	57	8.77	40	70.18
E	49	7.54	39	79.59

After getting suggestions from CCP, doctors assessed all the clinical evidences like, pathological and microbiological data, disease conditions, current signs and symptoms, recent physiological status and most possible optimum target of the treatment, and finally reconciled the prescriptions. In contrast with those CCP's clinical suggestions regarding the modifications of patients drug therapies in the prescriptions, under category- A, B, C, D and E, 73 suggestions (86.90%, n= 650), 88 suggestions (86.27%, n= 360), 326 suggestions (91.06%, n= 650), 40 suggestion (70.18%, n= 650) and 39 suggestions (79.59%, n= 650) (table 3) had been accepted and necessary adjustments in the prescriptions were accomplished by the doctors, accordingly. In response to those CCP's suggestions, the highest number of CCP's suggestions (326, n= 358) were accepted under category C (91.06%, n=358) (table 2) and the lowest number of CCP's suggestions (40, n= 57) were accepted under category D (70.18%, n= 57) (table 2) by doctors.

Table 3: Overall acceptances of CCP's suggestions by doctors

Total number of suggestions created by CCP (n)	Total number of suggestions accepted by doctors (n= 650)	Total suggestions accepted by doctors (%)	Total number of suggestions not accepted by doctors (n= 650)	Total suggestions not accepted by doctors (%)
650	566	87.08	84	12.92

After working on 828 patients, CCP generated 650 suggestions (table 1) for ICU's doctors during that 6-month period and among those suggestions, 566 (87.08%, n= 650) (table 3) suggestions were successfully accepted by doctors and prescriptions were modified, accordingly. On the other hand, 84 (12.92%, n= 650) (table 3) suggestions were not accepted by doctors.

DISCUSSION

Critical care pharmacist, the more specialized form of clinical pharmacist, has profound therapeutic knowledge and tremendous clinical efficiencies in order to play role in medication review, complicated therapeutic management, pharmacokinetic evaluation of medications and decision taking in crucial live saving times.[14] In this study, during the study period, the critical care pharmacist worked at general adult ICU department and reviewed 828 ICU's admitted critically ill patients' prescriptions thoroughly for finding possible modification of the drug therapies for ensuring medications' safety, accuracy and appropriateness. A critically ill patient in ICU setup is continuously monitored by ICU's multi professional team and the presence of poly pharmacy in the prescription is very common. Medication errors is the more or less frequently occurring fault in the poly pharmacy prescriptions of these patients and nurses sometimes do errors in medications' administration or dose calculation. Study shows that the presence of a responsible pharmacist in critical care areas like, ICU, is highly demandable in this perspective who can sensibly consider these issues and work for ensuring quality patient care.[15]

Studies found that among the ICU's multi professional team members, the importance of presence of clinical pharmacist was clearly distinguished through its quality patient care service, which ultimately represented the integrated better

treatment management for critically ill patients.[16, 17] Generally, patients at ICU always go through multiple disease conditions and use of complex poly pharmacy in these patients increase the chance of possible drug-drug interactions. A study found that clinical pharmacists are able to reduce 40% drug interactions by reviewing all ICU prescriptions and reduced incidences of drug interactions ensured quality doctors' prescriptions at ICU.[18] In our study, CCP provided 84(n=650) drug-drug interaction based suggestions and among those, 73 (86.90%) suggestions were accepted by doctors and modification of prescriptions were accomplished accordingly, which ultimately ensured the medication safety and enhanced the overall quality of prescriptions at ICU.

Sometimes, drug management in ICU patients become so critical for doctors specially when patients are found intolerable or unresponsive to existing drug therapies and require alteration or addition of new drug therapies for immediate management. In this study, during ICU grand round, CCP provided his suggestions (102, n=650) regarding new drug therapies when doctors are looking for additional new drug therapies for the management of critically ill patients and at that moment, those suggestions opened the doors of required treatment.

Body's fluid volume changes and one or more organ dysfunction in ICU's critically ill patients are mostly common, which ultimately alter the pharmacokinetics of many drugs including antibiotics and require dose adjustments.[19] A study found that antibiotics' doses adjustments according to the correspondent organ failure are managed perfectly by involving clinical pharmacist in the ICU's multi professional team and enhanced the activity of antimicrobial stewardship.[20] In the current study, CCP suggested highest 358 (55.08%, n=650) suggestions on antibiotic rational dosing and highest number of suggestions (326, 91.06%) were accepted by doctors in this regard. CCP continuously monitored prophylactic and therapeutic antibiotics of every patient; those were given immediately after patients' admission at ICU or at review stage after having microbiological reports. This study indicates that CCP's supports to doctors are highly required and effective for ensuring rational and appropriate use of antibiotics in critically ill patients which is essential for quality treatment of overall infections in ICU's patients. Other than antibiotics, general medications were also monitored by the CCP and among 57 suggestions on

medications' dose adjustment, 40 (70.18%) suggestions were accepted by doctors and prescriptions were reconciled accordingly, which justified an updated drug therapy management in concern with the current diagnosed disease conditions of critically ill patients. Multiple studies showed that medication errors during admission are observed among one third of patients and among 256 general medicine in-patients, every third patient's prescription has one or more unintentional medication discrepancies. So, clinical pharmacist's intervention ensures better medication management and associated drug safety.

Like medication errors in the prescription, drug induced adverse drug reactions (ADR) are another serious and life threatening incidences in poly pharmacy dependent patients of critical care areas like, ICU. Several studies showed that lower incidences of ADRs found among ICU's patients when clinical pharmacists are involved in ICU's multidisciplinary team.[23] CCP of the current study found 49 ADR incidences during the study at ICU and among those, 39 (79.59%) justified suggestions were accepted by doctors and ADR associated symptoms management therapies were applied, immediately. Continuous observation of patients in response to current medication therapies was the basic mechanism of CCP to identify suspected ADRs in patients and after complete justifications of the incidences, doctors reconciled the prescription, accordingly; that ultimately ensured patients' present and future medications' safety. The clinical pharmacist is the person who is selectively responsible for monitoring these adverse events in patients, to suggest the doctors for taking necessary management to overcome the incidence and to educate the patients regarding the occurred incidence and its proper management techniques in future.

Though this study did not focus on CCP induced cost reduction of medications of patients, but definitely a cost effective treatment management for every patient was observed through the inclusion of CCP's service at ICU. Globally, multiple studies found that intervention of clinical pharmacist at critical care areas ensured quality treatment with a significant treatment cost reduction phenomenon.[24, 25]

As a newly developing country, in Bangladesh, where pharmacists' roles in hospital settings are still a very new and not well familiarized profession, the provision of

having clinical pharmacist in multi professional team at local hospitals, are clearly a controversial, too much challenging and dreamy profession, nowadays. Nevertheless, the practice of clinical pharmacy has been initiated in the very few tertiary level hospitals in some mega-cities of Bangladesh and they are trying to ensure safe and appropriate drugs for the critically ill patients.

CONCLUSION

CCP can intervene in the ICU's complex therapeutic management as the core ICU-team member and through this contribution, medications' safety, appropriateness and accuracy are ensured, successfully. ICU doctors can frequently get clinical supports from CCP and closely adhering to this service, they can extremely upgrade their quality of prescriptions which ultimately ended into optimized quality of patient care.

CONFLICT OF INTEREST

There is no conflict of interest declared.

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Establishing ‘Cardiac Gym’ for rehabilitating cardiac patients undergone ‘By- pass surgery’ and ‘Stenting’ is a prime need.

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Heart disease has become the global cause of death accounting 17.3 million deaths per year, and the number is expected to grow to 23.6 million by 2030. At moment the disease has been designated as No1 cause of death in the world. In USA it is the leading cause of death accounting 1 in 7 deaths. According to the statistical survey report – 2014 the direct and indirect costs involved with cardiovascular diseases and stroke is approximately $320.1 billion per year. The figure includes expenses and loss of productivity [1]. It is now well agreed, in that, heart diseases has become threat to public health around the World and it is alarming. For Bangladesh scenario remains almost the same. According to the latest WHO data published in May 2014, deaths caused by Coronary Heart Disease in Bangladesh reached 50,708 meaning 6.96% of total deaths and the age adjusted death rate was 53.53 per 100,000 of population [2]. Such picture is very frightening as compared to the past. In the past incidences of prevalence and mortality was much less as compared to current scenario. Such worsening of situation may be due to the complexity of modern life. Here life is advancing in almost in a mechanical speed and hence shortcomings are also occurring in a higher speed. Now a days modern life is succumbed with anxieties, worries, wearing and tearing. These factors surely potentiate the prevalence of cardiac disease. But life can not be stranded at still. It should be propelled. Continuous measures had been and still being taken by the physicians, researchers, formulators and pharmacists to reduce the severity and incidences of the problems. Among the measures adopted ‘Surgical intervention’ (i.e. ‘By - pass surgery’) and ‘Stenting’ (i.e. ‘angioplasty’) are two major ones. These measures are adopted to improve blood flow in the coronary artery which has become narrowed. Such narrowing of blood vessel could be due to many reasons and one most frequent reason is the formation of ‘plaque’ (a composite formed mainly by lipid materials and blood cells) inside the coronary

blood vessels. ‘By-pass surgery’ creates an alternate route for blood to flow. But the process seems fearful to a patient as it needs general anaesthesia and surgical opening of the chest. Not only that recovery period is also long. On the contrary ‘Stenting’ involves placing of a tiny pipe like structure made up with metal mesh into the plaque present in the vessel. This procedure is with less discomfort, less fearful and recovery time is short. Under local anasethesia and mild anasethesia stents can be placed without opening the chest. The procedure is called ‘Percutaneous coronary intervention’ [3]. Of course after having ‘By- pass surgery’ or ‘Stenting’, a patient gets a new life indeed, but unfortunately, s/he will not be risk free. At any time the process may fail. So the theory of “Life’s Simple 7” has been made and is suggested to follow. This theory is based on seven principles if one wants to reduce the prevalence and mortality caused by cardiac problems and these are in simpler forms ‘quit smoking’, ‘have physical activities’ meaning ‘do exercise’, ‘take healthy diet’, ‘control body weight’, ‘maintain normal cholesterol and sugar level’ in blood and lastly ‘control and maintain blood pressure’ [1]. For a cardiac patient undergone ‘by-pass surgery’ or ‘stenting’ taking physical exercise in a regular fashion along with proper diet control is of utmost importance. Proper physical exercise can make body ‘fit’ and also can relieve tension and can give free mind to enjoy. But in Dhaka where to do exercise. In Dhaka it is very difficult to find free space to do physical exercise. People can go to parks. But the number of parks in Dhaka is very limited and almost next to zero (compared to population and areas). People can go to ‘Gymnasium’. But it is not suitable for the cardiac patients those who have undergone surgery or stenting recently. They should excise or even walk under strict supervision of a cardiologist. Because during exercise body functionality changes and blood pressure, pulse also changes. Here duration of exercising and equipment involved with exercise are important to consider. Here the conditions of the patient undergone such surgical intervention or stenting should be monitored strictly during the period of exercise and that an experienced cardiologist can do only. Here the expert cardiologist can select the time period and the necessary equipment.

Again some cardiologists suggests intake of pressure lowering medicines in the morning. Because people works during the day time and may face mental pressure which may need the presence of a pressure controlling agent at that time. On the contrary some says it is better to have the medicines at bed time. Here drugs that are susceptible to diurnal variation at this time suffers minimum from that effect. So pharmacokinetic parameters of drug would be stable and drug action would be more. Considering the gravity of the situation therefore establishing a 'Rehabilitation centre' or 'Green Heart gym' under strict supervision of experienced cardiologists for cardiac patients undergone 'By- pass surgery' and 'Stenting' is an emergency.

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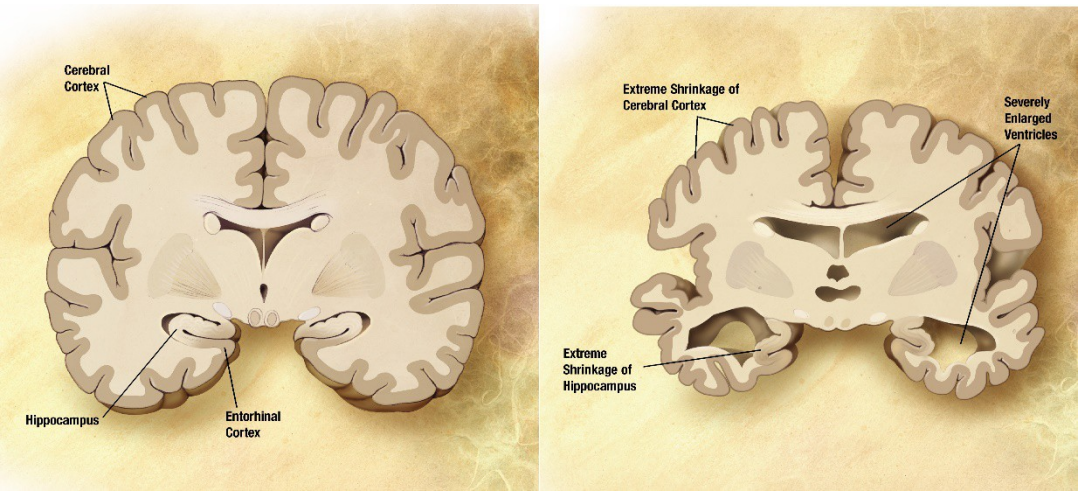
Alzheimer's and Dementia

Why we should pay attention to our brain health.

Kazi Anam, M.S., R.Ph.,FASCP, ND, CCN, CH, CI

It is estimated that worldwide about 50 million individuals have some type of dementia and 10 million new cases are diagnosed with some type of dementia.
More and more individuals are now living beyond 80.
That is when Alzheimer's and other dementia are most prevalent.
So this makes total sense to pay attention to our brain health and cognitive functions.

German Psychiatrist and Neuropathologist Dr. Alois Alzheimer first published a case about a female patient in1906. He noticed changes in the brain of a female patient who died of an unusual mental illness.
Her symptoms included memory loss, language problems, as well as some unpredictable unusual behavior.
After she died and her brain was examined, he found many abnormal clumps, which is now known as amyloid plaques. He also found tangled bundles of fibers, now known as Tau tangles.
These Plaques and tangles are the prominent features of Alzheimer's disease.
Another issue is the impaired connections between nerve cells or neurons in the brain.
Neurons usually transmit information in the brain as well as to muscles and organs in the body.



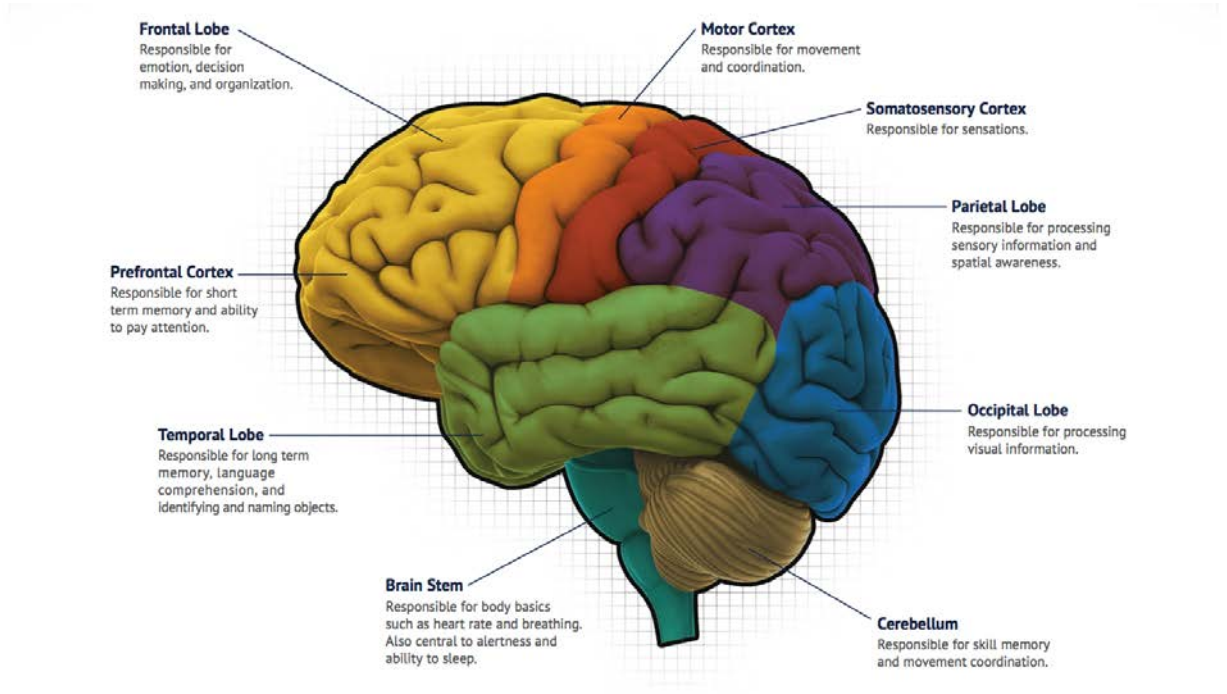
Alzheimer's disease is a chronic progressive brain disorder that gradually destroys memory and thinking capacity and eventually it becomes impossible even to carry out simple daily tasks of eating, dressing up etc.

Alzheimer's disease is also considered as the cause of dementia - a continuous impairment in thinking and memory that interferes with a person's daily life.

Dementia has many different stages. In the beginning it is the mild stage when it is just beginning to interfere with a person's basic activities to the most advanced stage when the person cannot do the basic activities of daily life.

There are about 11 types of dementia.

Alzheimer's disease is the most common type of dementia. According to Alzheimer's Association about 60 to 80 percent cases of dementia are caused by Alzheimer's.



Types of dementia:

According to the Alzheimer's Association there are about 11 types of dementia.

1. Vascular dementia:

This is the second most common type of dementia.
Up to 10 percent cases of dementia are considered as vascular dementia.
In this type of dementia a decline in thinking skills are caused by cerebrovascular disease, a condition when blood vessels in the brain are damaged and brain tissue injured, depriving brain cells oxygen and nutrients. Impaired blood flow can damage and eventually kill cells anywhere in the body. The brain has a rich network of blood vessels and impaired blood flow can damage and eventually kill cells anywhere in the body.
In vascular dementia, changes in thinking skills sometimes occur suddenly following stroke that block major blood vessels in the brain.
Thinking problems may also begin as mild changes that worsen slowly when a person experiences several mini-strokes or other issues when circulation is impaired.

2. Frontotemporal dementia:
In this dementia progressive nerve cell damage occurs in the brain's frontal lobes or the temporal lobes. The nerve cell damage in this area leads to loss of function in these regions of the brain. This causes deterioration in behavior, personality and language.
There are two groups of protein, tau protein and TDP43 protein that has preference to damage the nerve cells in these regions of brain.
Frontotemporal dementia is also known as Pick's disease.
In 1892 Dr. Arnold Pick, M.D. first described a patient with specific symptoms affecting language.

3. Lewy Body dementia:
This is a type of dementia that usually leads to decline in thinking capacity, reasoning and independent function due to abnormal deposits that damage brain cells over time.
This is most likely the third common cause of dementia followed by Alzheimer's and vascular dementia.
This dementia was first reported by Dr. Frederich H. Lewy M.D. while working with
Dr. Alois Alzheimer's in early part of 1900s. Alpha-synuclean protein, the main component of Lewy bodies is widely distributed in the brain. Its full function is not known yet. These Lewy bodies are also seen in other brain disorders including Parkinson's disease dementia. Parkinson's disease can eventually lead to problems with thinking and reasoning. Many individuals with Parkinson's develop movement symptoms which may include posture, rigid muscles and difficulty in walking. Most likely alpha-synuclein protein is responsible for these type dementia. At the same time many individuals with

Lewis body dementia and Parkinson's dementia develops plaques and tangles which is the primary brain changes linked to Alzheimer's disease.

4. Posterior Cortical Atrophy:

This type of dementia affects the outer layer of the brain, located in the back of the head. With this disease the affected part of the brain shows amyloid plaques as well as neurofibrillary tangles due to tau protein. Although most cases of Alzheimer's usually develop after age 65, this type of dementia can be seen in individuals as early as 50.

5. Normal Pressure Hydrocephalus:

This is a brain disorder where cerebrospinal fluid accumulates in the ventricles of the brain that causes ventricles in the brain to become enlarged, resulting in thinking and reasoning problems. Most prominent attributes to this type of dementia are gait disturbances, impaired mental capacity and impaired bladder control.

This type of dementia often affects individuals over 60. In many cases this is caused by some other type of brain disorders like tumor, brain injury and hemorrhage or inflammation.

6. Creutzfeldt-Jakob disease (CJD):

This is considered as a very rare, degenerative, fatal brain disorder. According to NIH it affects about one person in every one million worldwide. In the United States there are about 350 cases per year. The onset of this disorder occurs after age 60 and about 70 percent affected dies within a year. In its early stages it affects memory, causes behavioral changes, lack of coordination and visual impairment. As the disease progresses, mental capacity continues to decline, develops involuntary movements, blindness, weakness of extremities and coma may occur.

There are three main types of CJD: Sporadic CJD, Hereditary CJD and acquired CJD. Sporadic CJD can happen without any known risk factors and about 85% of CJD belongs to this class.

Hereditary CJD is caused primarily due to heredity and genetic mutation associated with this. According to NIH about 10 to 15 percent of CJD cases fall in this category.

In acquired CJD, the disease is usually transmitted by exposure to brain or nervous system. A variant CJD can be acquired by eating meat from cattle affected by bovine spongiform encephalopathy, which is commonly referred as "Mad Cow" disease.

7. Huntington Disease:

Huntington disease is named after Dr.George Huntington who described this disease in 1872.

This is a progressive brain disorder caused by a defective gene, that causes uncontrolled movements, emotional problems and thinking ability. The most common form of this disorder usually appears in the 30's and 40's, characterized by irritability, depression, small involuntary movements, poor coordination and difficulty in learning new information or the decision making process. The brain changes in the Huntington disease may also lead to mood swing, anger and irritability, as well as obsessive-complusive behavior.

A relatively less common form of Huntington disease known as Juvenile form develops in childhood and adolescence.

Typically, juvenile form manifests slow movements, clumsiness, frequent falling, rigidity, slurred speech and drooling.

8. Korsakoff Syndrome:

This is a chronic degenerative brain disorder caused by severe thiamine (Vitamin B-1) deficiency. This deficiency may result from alcohol abuse, dietary deficiencies, prolonged vomiting, eating disorders or the side effect of chemotherapy. Thiamin (vitamin B-1) deficiency causes damage to the brain's thalamus and hypothalamus. Typical symptoms are mental confusion, vision problems, coma, hypothermia, low blood pressure and lack of muscle coordination. Korsakoff syndrome damages nerve cells and supporting cells in the brain and spinal cord as well as the part of the brain involved with memory. This also causes difficulties in learning new information, inability to remember recent events and long term memory.

9. Parkinson's disease dementia:

Parkinson's disease is a neurodegenerative disorder that affects predominantly dopamine-producing neurons in a specific area of the brain called substantia nigra.

This area of brain plays a key role in movement, leading to early symptoms that include tremors and shakiness, muscle stiffness, a shuffling step, stooped posture, difficulty in movement and lack of facial expression. As brain changes worsens they often affect mental functions, including memory and the ability to pay attention, make sound judgements and plan the steps needed to complete a task. The key brain changes in

Parkinson's disease dementia are abnormal microscopic deposits primarily composed of alpha-synuclein, a protein widely found in the brain.
There are several stages of Parkinson's disease.
Stage 5 is considered as the most advanced and debilitating stage.
In this stage stiffness in legs may make it practically impossible to stand or walk.
The person could be wheelchair bound or bedridden.

10. Down syndrome dementia:

Individuals with Down syndrome are born with an extra copy of chromosome 21, which carries the APP gene. This gene produces a specific protein known as amyloid precursor protein (APP). Too much APP protein leads to a buildup of protein clumps called beta-amyloid plaques in the brain. By the time a person with Down syndrome turns 40, it is expected that they have significant amount of this plaques, along with other protein deposits, called tau tangles, which cause problems with how brain cells function and increase the risk of developing Alzheimer's disease.
Just to mention, not all individuals with these brain plaques will develop symptoms of Alzheimers. Estimates suggest about 50 percent or more of individuals with Down syndrome will develop dementia due to Alzheimer's disease as they age.

11. Mixed Dementia:

It is very common for people with dementia to have mixed dementia. A combination of two or more types of dementia. Many different combinations are seen. Some people could have both Alzheimer's and Huntington's or Alzheimer's and vascular dementia.
Autopsy studies for individuals over 80 reflect that brains of people who had dementia most likely had some type of mixed dementia caused by a combination of degenerative brain changes.
In individuals with mixed dementia, it may not be clear what percentage of symptoms are due to Alzheimer's or another form of dementia. However one study found that 78 percent had 2 or more disease characteristics in the brain. Alzheimer's was the most common neurodegenerative disease, but rarely occurred alone.

Risk factors and what can be done to reduce chances of developing Alzheimer's or any other dementia:

A healthy lifestyle can help reduce the risk of Alzheimer's disease and other types of dementia. It has been estimated that up to half the cases of Alzheimer's disease worldwide may be the result of seven key modifiable risk factors: Cognitive inactivity, depression, diabetes, high blood pressure, obesity, smoking and physical inactivity. What a person can do to improve brain health? These are the steps recommended:

- Be physically active
- Avoid smoking and excessive alcohol consumption
- Keep blood pressure, cholesterol, blood sugar and weight within recommended range.
- Stay connected socially and interact with others regularly.
- Make healthy food choices, eat a well-balanced and healthy diet with greens, whole grains, fish, legumes and vegetable.
- Manage stress levels.
- Engage in some type of lifelong learning.
- Do crossword puzzle.
- Learn to play some type of musical instrument.
- Learn a new language.
- Always challenge the brain.

Supplements that can boost memory and brain function:

- Omega-3 fish oil.
- Lecithin (sunflower lecithin is preferred over Soy)
- Phosphodylserine
- Vitamin B-Complex
- Resveratrol
- Acetyl L-Carnitine
-

Foods that are good for memory:

- Organic Coconut oil
- All types of berries
- All types of Nuts

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3D Printing in Pharmaceutical Formulation: A New Platform towards Precision Medicine

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Three-dimensional (3D) printing is a very recent innovation in pharmaceutical formulation that has emerged as one of the most revolutionary and powerful tools towards precision medicine. 3D printing is an additive manufacturing (AM) technique that can build 3D objects by sequential deposition of layers programmed with a computer aided design (CAD). The technology has opened endless opportunities for the development of personalized medicines and orphan drugs. Despite of unprecedented patient-benefits, this promising method is not completely devoid of drawbacks. To overcome the challenges, strict regulatory control and extensive research is necessary to make the technique industrially feasible for drug formulation.

Patient-Centric Drug Development

Precision medicine is an approach that allows doctors to select treatments that are most likely to help patients based on a genetic understanding of their disease. This relatively new branch of therapy is also known as personalized medicine. Inter-personal variability is an increasingly global problem when treating patients from different socio-economic, cultural, metabolic and genetic make-ups. Pharmacogenomics uses information about a person's genetic makeup, to choose the drugs that are likely to work best for that particular person. This new field combines the science of how drugs work (pharmacology) with the science of the human genome, called genomics.

In recent years, patient-centric dosage form design is a noticeable trend in pharmaceutical formulation. Growing demand for customized devices fueled by the modern technological advancements and increased public-private funding are the key factors making the major progress in personalized medicines. Formulation scientists are constantly motivated towards new concepts in drug design, better understanding of material properties, manufacturing technology and processes that assures the best quality dosage forms.

Until recently, drugs have been developed with the idea that each drug works pretty much the same way in every single patient. But genomic research has changed that "*one size fits all*" approach and opened the door to more *personalized* approaches to using and developing drugs. Depending on your genetic makeup, some drugs may work more or less effectively for you than they do in other people. Likewise, some drugs may produce more or fewer side effects in you than in someone else.

Heterogeneous nature of diseases is a major source of difficulties in therapeutic intervention. Failures or limitations of therapeutic effects are some of the reasons to modify the dosage form as well as dose of the active substance especially for individual age groups. The appropriate dosage form need to be selected considering physicochemical properties of drug molecules as well as target population and treated diseases. In recent years, these factors contributed significantly towards more individualized and customized dosage form alternatives such as 3D printed tablets, capsules, implants and orodispersible films.

Orphan Drugs

Diseases that are very rare and found in less than 200,000 patients in the United States are known as orphan diseases, which is the cutoff point for the number of patients for a drug to be profitable. Because many thousands of orphan diseases exist in the aggregate (about 20 to 30 million Americans have orphan diseases), these patients are disenfranchised from drug development by the pharmaceutical industries. The orphan diseases are often so rare that a physician may observe only 1 case a year or less. So proper treatment is a personalized encounter between doctor and patient.

The FDA Office of Orphan Products Development (OOPD) mission is to advance the evaluation and development of products (drugs, biologics, devices, or medical foods) that demonstrate promise for the diagnosis and/or treatment of rare diseases or conditions. In fulfilling that task, OOPD evaluates scientific and clinical data submissions from sponsors to identify and designate products as promising for rare disease and to further advance scientific development of such promising medical products.

Orphan diseases and orphan drugs are most important contributing factors towards the development of personalized therapy and customized dosage forms. 3D printing holds tremendous promise for orphan drugs, designed to treat very small group of patients that are usually not developed by the pharmaceutical industry due to economic reasons. As a result, Orphan drugs currently occupy a large part of personalized medicine.

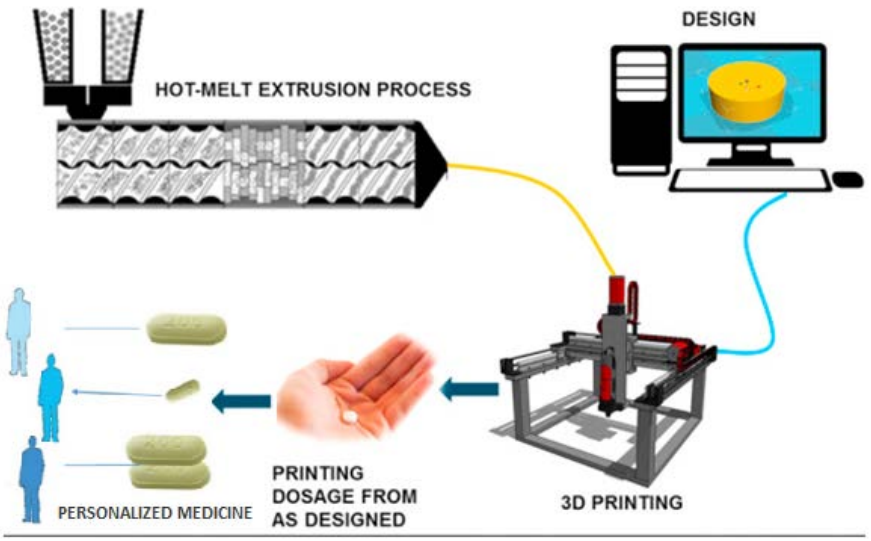

Figure 1: Lay out of 3D printing tablet

3D Printed Drug Products

Three-dimensional (3D) printing is a form of additive manufacturing (AM) programmed with a computer aided design (CAD) wherein a structure is built by depositing or binding materials in successive layers to produce a 3D object (**Figure 1**). With the simultaneous ascending trend in patient-centric drug product development found within the last decade, 3D printing is now one of the fastest developing branches of technology, art and science. As mentioned earlier, In contrast to commonly used subtractive and formative manufacturing methodologies, this technique is an additive manufacturing technique in which the parts are prepared from 3D model data in the process of joining materials layer by layer. The practical approach of AM is called rapid prototyping (RP) and its advantages include the reduction of prototyping time and costs, easy modifications of a product at a designed level, the possibility of manufacturing of small objects, individualized product series or structures impossible to be formed with subtractive techniques.

Potential benefits of 3D additive manufacturing

- Direct digital manufacturing
- Accurate control of spatial distribution of API in the dosage form
- Production of complex geometries,
- Depositing very small amount of API,
- Reduction of manufacturing waste,
- Preparation of individualized dosage strength,
- Avoiding traditional complex supply chain etc.

Looking Back at History

The idea of 3D printing has evolved in early 70's of the 20th century when Pierre A. L. Ciraud described the method of application of powdered material and subsequent solidification of each layer through the action of high energy beam. At the end of 80's Scott Crump filed a patent for fused deposition modelling (FDM) – a technique which used thermoplastic material for object preparation. In the 90's Emanuel Sachs and co-workers at MIT patented 3-dimensional printing technique based on joining the selected regions of powder by binding material.

The first orally disintegrating 3D printed tablet, Spritam® (levetiracetam)-an anti-epileptic drug, was approved by U.S. Food and Drug Administration in 2015 and subsequently, the interest in pharmaceutical sector for 3D printing has been growing very rapidly. Several 3D printing platforms have been reported in the literature for producing pharmaceutical dosage forms, including fused deposition modelling (FDM), three-dimensional printing™, inkjet 3D printing, thermal inkjet 2D printing and stereolithographic 3D printing.

Smart manufacturers are constantly investing in 3D-printing research, while new entrepreneurs are also breaking into the pharmaceutical space. Such experiments can open the doors for personalized medicine and improvements in clinical trials, benefitting patients as well as manufacturers.

How 3DP Works in Tableting

Among almost 4-decades of 3DP history many different techniques were developed and evolved with the technological progress. The main methods are based on powder solidification, liquid solidification, & hot melt extrusion (HME).

Currently two modes of printing method are in practice – (1) extrusion of semisolid, or semi-molten materials (gels, pastes) at room or elevated temperature, & (2) extrusion of molten thermoplastic rod-shape material (filament). In both modes the material is extruded from the nozzle and spread in subsequent layers on the surface of build platform. Defined dimension of printed path is created by the distance of print head to the build plate and influenced by the nozzle orifice diameter. These two parameters and print speed affect the quality of printed object.

Hot melt extrusion (HME) as well as extrusion of semisolid materials are still the methods of choice for the formulation of pharmaceutical products. The filament quality attributes like

constant dimension, elasticity, stiffness, homogenous drug distribution are of key importance in the development of printed dosage form by using FDM method. Nowadays, HME is a main way to obtain good-quality filaments containing APIs, however the first attempts of FDM method application were based on ready-to-use, commercially available filaments for 3D printers. Model drugs were incorporated into the filaments by swelling filament involatile solvent solution of API and drying. This approach allowed to prepare first 3D-printed dosage form by FDM method.

Each 3D printer which works according to a different mode requires sufficient material to be solidified and subsequent object fabrication. Despite of the diversity of 3DP methods, preparation of 3D-printed object in general, includes the following basic steps:

- the design of 3D object with computer-aided design software and optimization of the geometry according to printer specification,
- the export of 3D model to a common and printer recognizable file format that includes only 3D geometry,
- the import of the file to the software and generation of layers which will be printed; the height of the printed layer essentially influences the quality of the printed object as well as printing time, &
- the fabrication of the object by subsequent application (or solidification) of the material layers dedicated to the specific printing method.

The steps followed in the manufacturing of tablets, in particular, by using micro-extrusion 3D printing includes the following: i) preparation of drug loaded pastes, ii) micro-extrusion of fine paste into printing filaments, iii) filament deposition into a 3D structure per the selected design, iv) post-processing treatment for solvent evaporation and v) solidification and desiccation into final dosage unit. Preparation of a paste of a drug in a given formulation is a simple process that employs various fine powders in combination with a proper binder liquid(s). For tablet manufacturing, 3D printing pastes may be considered as intermediate product.

3D Printed Polypill

The concept of “polypill” refers to a single tablet that includes the combination of several drugs. Therefore, it provides huge benefits in polymedicated patients, such as the elderly. Different

polypills using 3D extrusion printing have been successfully created. As an example, captopril, nifedipine, and glipizide, to treat hypertension and type 2 diabetes, have been manufactured in a single pill by using 3D printing. The technology has moved forward and currently, prototypes including five different types of APIs with different release profiles have been produced. Researchers suggest 3D printing can be part of the pharmacy's future, too. If common medications for chronic diseases were available in a pharmacist's 3D printer, a customized "polypill" could be created that could potentially contain all the medications a patient needs in one pill.

Conclusion

Potential threats in 3DP in pharma sectors are lack of suitable polymer, poor drug-release profile, cost-inefficiency, lack of regulatory control, socio-ethical concerns etc. Despite of these potential challenges, 3D Printing is considered to be the newest installation in pharmaceutical manufacturing. With applications in controlled release, short-run medicines, and even the potential for on-site printing at pharmacies, 3D-printing technology deserves the opportunity to provide the pharmaceutical industries with a more dynamic and innovative platform towards precision medicine.

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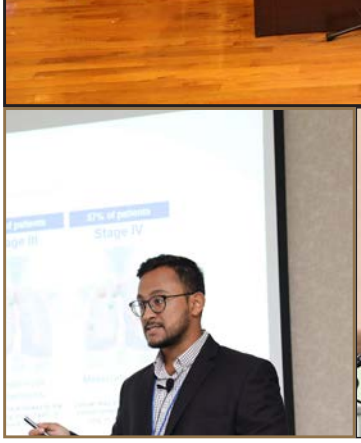

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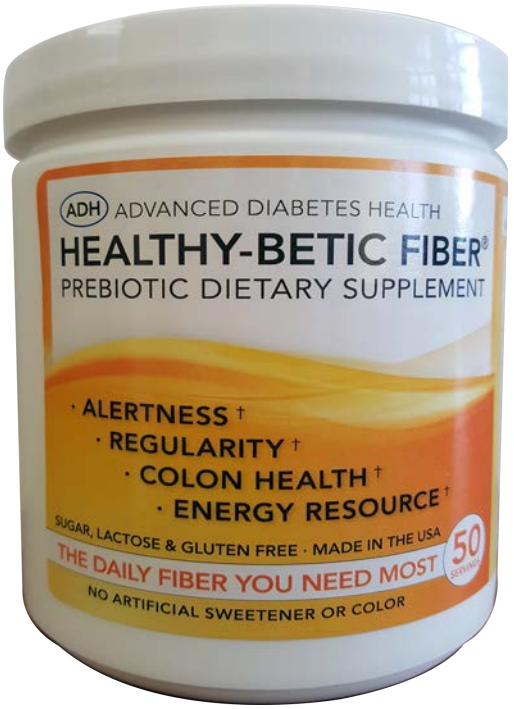

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